UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

- - -

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	:	MDL No. 2804
_____	:	Case No. 1:17-MD-2804
THIS DOCUMENT RELATES TO ALL CASES	:	Hon. Dan A. Polster

- - -

Thursday, December 6, 2018

HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

- - -

Videotaped deposition of JASON BRISCOE, held at the offices of Cavitch, Familo & Durkin, 1300 East Ninth Street, Cleveland, Ohio, commencing at 9:05 a.m., on the above date, before Carol A. Kirk, Registered Merit Reporter and Notary Public.

- - -

GOLKOW LITIGATION SERVICES
877.370.3377 ph | 917.591.5672 fax
deps@golkow.com

A P P E A R A N C E S:

On behalf of the Plaintiffs:
LEVIN PAPANTONIO THOMAS MITCHELL
RAFFERTY & PROCTOR P.A.
BY: PETER MOUGEY, ESQUIRE
pmougey@levinlaw.com
JEFF GADDY, ESQUIRE (via live stream)
jgaddy@levinlaw.com
PAGE POERSCHKE, ESQUIRE (via live stream)
ppoerschke@levinlaw.com
316 South Baylen Street, Suite 600
Pensacola, Florida 32502
205-435-7000
and
COHEN & MALAD, LLP
BY: GABRIEL A. HAWKINS, ESQUIRE
ghawkins@cohenandmalad.com
One Indiana Square, Suite 1400
Indianapolis, Indiana 46204
317-636-6481

On behalf of Discount Drug Mart:
CAVITCH FAMILO & DURKIN, LPA
BY: TIMOTHY JOHNSON, ESQUIRE
tjohnson@cavitch.com
GREGORY O'BRIEN, ESQUIRE
gobrien@cavitch.com
1300 East Ninth Street, 20th Floor
Cleveland, Ohio 44114
216-621-7860

On behalf of the Cardinal Health, Inc. (via teleconference and live stream):
WILLIAMS & CONNOLLY LLP
BY: SUZANNE SALGADO, ESQUIRE
ssalgado@wc.com
725 Twelfth Street, N.W.
Washington, DC 20005
202-434-5000

On behalf of the AmerisourceBergen:
JACKSON KELLY PLLC
BY: SANDRA K. ZERRUSEN, ESQUIRE
skzerrusen@jacksonkelly.com
50 South Main Street, Suite 201
Akron, Ohio 44308
330-252-9060

On behalf of HBC:
MARCUS & SHAPIRA LLP
BY: MOIRA CAIN-MANNIX, ESQUIRE
cain-mannix@marcus-shapira.com
One Oxford Center, 35th Floor
301 Grant Street
Pittsburgh, Pennsylvania 15219-6401
412-338-3344

On behalf of Walmart (via teleconference):
JONES DAY
BY: SCOTT D. QUELLHORST, ESQUIRE
squellhorst@jonesday.com
77 West Wacker Drive
Chicago, Illinois 60601
312-782-3939

On behalf of Endo Pharmaceuticals, Inc. and Endo Health Solutions Inc. (via live stream and teleconference):
ARNOLD & PORTER KAYE SCHOLER, LLP
BY: JAKE R. MILLER, ESQUIRE
jake.miller@apks.com
777 S. Figueroa Street, Suite 4400
Los Angeles, California 90017
213-243-4000

On behalf of the Allergan Defendants (via live stream and teleconference):
KIRKLAND & ELLIS LLP
BY: KAITLYN L. COVERSTONE, ESQUIRE
kaitlyn.coverstone@kirkland.com
300 North LaSalle
Chicago, Illinois 60654
312-862-3671

On behalf of Johnson & Johnson and Janssen Pharmaceuticals:
TUCKER ELLIS LLP
BY: BRENDA A. SWEET, ESQUIRE
brenda.sweet@tuckerellis.com
950 Main Avenue, Suite 1100
Cleveland, Ohio 44113
216-592-5000

On behalf of McKesson:
ULMER & BERNE, LLP
BY: DOLORES (LOLA) GARCIA-PRIGNITZ, ESQUIRE
dgarcia-prignitz@ulmer.com
1660 West 2nd Street, Suite 1100
Cleveland, Ohio 44113
216-583-7000

On behalf of Mallinckrodt (via live stream):
ROPES & GRAY LLP
BY: SEAN B. KENNEDY, ESQUIRE
sean.kennedy@ropesgray.com
800 Boyleston Street
Boston, Massachusetts 02199
614-951-7000

On behalf of Pernix Therapeutics:
CLARK MICHIE LLP
BY: BRUCE CLARK, ESQUIRE
bruce.clark@clarkmichie.com
220 Alexander Street
Princeton, New Jersey 08540
609-423-2142

ALSO PRESENT:
Madison Shelquist, Levin Papantonio
Karolynn Schneegas, Levin Papantonio
Alexandra Garlock, Levin Papantonio
Katie Mayo, Levin Papantonio (via live stream)
Josh Gay, Levin Papantonio (via live stream)
Tom McConnell, Discount Drug Mart
David Lane, Videographer
Corey Smith, Trial Technician

- - -

VIDEOTAPED DEPOSITION OF JASON BRISCOE

INDEX TO EXAMINATION

VIDEOTAPED DEPOSITION OF JASON BRISCOE

INDEX TO EXHIBITS

INDEX TO EXHIBITS (CONT'D)

INDEX TO EXHIBITS (CONT'D)

- - -

P R O C E E D I N G S

- - -

THE VIDEOGRAPHER: We're now on the record. My name is David Lane, videographer for Golkow Litigation Services. Today's date is December 6th, 2018. Our time is 9:05 a.m.

This deposition is taking place in Cleveland, Ohio, in the matter of: National Prescription Opiate Litigation MDL. Our deponent today is Jason Briscoe. Counsel will be noted on the stenographic record. The court reporter is Carol Kirk, who will now swear in the witness.

(Witness sworn.)

THE VIDEOGRAPHER: Please begin.

MR. MOUGEY: Do you mind if we go around and get everybody on the -- or do we already have that, who's here?

MR. JOHNSON: Oh, just to introduce ourselves?

MR. MOUGEY: Yeah, that would be

great.

MR. JOHNSON: Okay. I'm Tim Johnson. I represent Discount Drug Mart.

MR. O'BRIEN: Greg O'Brien. I'm also representing Drug Mart.

MR. McCONNELL: I'm Tom McConnell. I'm with Discount Drug Mart as corporate representative.

MS. CAIN-MANNIX: Moira Cain-Mannix from Marcus & Shapira on behalf of HBC Services Company.

MS. GARCIA-PRIGNITZ: Dolores Garcia-Prignitz of Ulmer & Berne on behalf of McKesson Corporation.

MS. SWEET: Brenda Sweet of Tucker Ellis LLP on behalf of Janssen Pharmaceuticals and Johnson & Johnson.

MS. ZERRUSEN: Sandra Zerrusen from Jackson Kelly on behalf of AmerisourceBergen Drug Corporation.

MS. SHELQUIST: Madison Shelquist on behalf of Levin Papantonio representing the Plaintiff.

MS. SCHNEEGAS: Karolynn Schneegas on behalf of Plaintiff.

MR. HAWKINS: Gabe Hawkins, Plaintiff.

MS. GARLOCK: Alexandra Garlock, Plaintiff.

MR. MOUGEY: And Peter Mougey on behalf of the Plaintiff. Thank you.

- - -

JASON BRISCOE

being by me first duly sworn, as hereinafter certified, deposes and says as follows:

DIRECT EXAMINATION

BY MR. MOUGEY:

Q. Good morning, Mr. Briscoe. My name is Peter Mougey. I represent the Plaintiffs in this case.

Have you ever given a deposition before?

MS. COVERSTONE: Excuse me. I'd like to enter my appearance. This is Kaitlyn Coverstone on behalf of Allergan Finance, LLC.

MR. QUELLHORST: And Scott

Quellhorst with Jones Day on behalf of Walmart.

MS. SALGADO: Suzanne Salgado on behalf of Cardinal Health.

MR. MILLER: Hi. This is Jake Miller on behalf of the Endo and Par Pharmaceutical Defendants, and I am with the law firm Arnold & Porter.

BY MR. MOUGEY:

Q. Okay. Good morning. Peter Mougey on behalf of the Plaintiffs.

Have you ever given testimony in any deposition or sworn statement?

A. I have not.

Q. Okay. One thing I'm going to guarantee you through the course of the day is that I will interrupt you before you're finished speaking. So if you take a breath and I think you're done and you're not, just stop me and say, "I had more to my answer."

I don't mean to interrupt you or be rude or anything else, but I just tend to -- tend to speak quickly and I'll -- if you take a break, I'll keep going. Okay?

- - -

(DDM-Briscoe Exhibit 1 marked.)

- - -

BY MR. MOUGEY:

Q. I'm going to hand you what I have marked as Briscoe 1, which is titled your -- it's Amended Notice of Oral Videotaped 30(b)(6) Deposition with your name on top of that, okay?

And if you look in the fourth paragraph, it says, "The oral examination is to be taken for purposes of discovery, for use at trial, or for such other purposes as permitted under the federal rules of evidence."

Do you see that?

A. Yes, sir.

Q. And your name on top, Jason Briscoe, correct?

A. Yes.

Q. And you understand today that you are representing Walgreens?

A. I'm not.

Q. I'm sorry. You're -- well, DDM.

MR. JOHNSON: You're in the wrong city.

MR. MOUGEY: Yeah, same city, different --

Q. DDM, correct?

A. Yes, sir.

Q. And at Discount Drug Mart, you are the corporate representative speaking on behalf of Discount Drug Mart, correct?

A. One of the three 30(b)(6), yes.

Q. Yes, sir. And that -- you've heard the saying before, you know, you wear -- you wear different hats, so to speak, maybe at the office or wherever else. You're familiar with that saying?

A. Yes, sir.

Q. All right. So you have your -- your personal capacity is Jason Briscoe, which is your personal knowledge and you also have your capacity today that you represent DDM or Discount Drug Mart, correct?

A. Yes.

Q. So the answers that you provide today, you are speaking on behalf of Discount Drug Mart, not in your personal capacity as Jason Briscoe.

You understand that?

A. I do.

Q. Okay. And you see in the second paragraph of Briscoe 1 that there are a series of numbers in that paragraph designating specific topics that you and I are going to go through today, correct?

A. Yes, sir.

Q. It -- I'll hand you what --

MR. JOHNSON: With the exception of Number 10 that we discussed off the record before we started, right, Peter?

MR. MOUGEY: Exactly. Exactly. So we'll go through those.

- - -

(DDM-Briscoe Exhibit 2 marked.)

- - -

BY MR. MOUGEY:

Q. I'll hand you what we'll mark as Briscoe 2.

A. Three copies of the same document, sir?

Q. Yes.

A. Okay.

MR. MOUGEY: All right. Briscoe 2 is 1011, Corey.

And, Corey, I'm sorry. It's 1002.

Nope. One more time. 1001.

There we go.

BY MR. MOUGEY:

Q. And this is titled First Notice of Deposition Pursuant to Rule 30(B)(6) and Document Request Pursuant to Rule 30(B)(2), correct?

And you've seen this before, correct?

A. I have.

Q. And under the second paragraph on the first page of Briscoe 2, it says, "Pursuant to Federal Rules of Civil Procedure 30(b)(6), Discount Drug shall designate and produce a representative or representatives, as may be required, who are knowledgeable and prepared to testify fully on behalf of Discount Drug concerning the topics identified in Schedule A below."

Do you see that?

A. Yes, sir.

Q. All right. And if you turn to page 2 of Briscoe 2, it has -- there's a section titled Duty to Prepare. And the Duty to Prepare, "The testimony elicited in the deposition represents Discount Drug's knowledge, not the individual deponent's knowledge. Discount Drug must conduct a thorough investigation in response to the deposition notice and must prepare a witness to testify to all matters known or reasonably available to the organization."

Did I read that right?

A. Yes, sir.

Q. All right. "Therefore, if Discount Drug's designee is not knowledgeable about the matters specified in the deposition notice, it must nonetheless prepare such designee to give knowledgeable, binding answers."

And by "knowledgeable" and "binding," meaning when you speak today on behalf of DDM, you are binding the corporation with your answers.

You understand that, correct, sir?

A. Yes, sir.

Q. The paragraph continues, "Reasonably available information includes all documents that the organization has the authority, legal right, or practical ability to obtain. An inadequately prepared designated witness will amount to an impermissible refusal to answer and a sanctionable failure to appear."

And you understand that, correct, sir?

A. Yes, sir.

Q. All right. And if we go back to the title of that paragraph, Duty to Prepare, sir, have you, in fact, prepared for your testimony today?

A. I have.

Q. All right. And do you have a -- kind of a general understanding of how many hours you've spent preparing for your testimony today?

A. Eight to ten.

Q. Eight to ten hours.

And when did you start preparing for your testimony today?

A. I suppose when we first heard of the case and I was designated as a 30(b)(6).

Q. Okay. So for over the last couple of months, last few months?

A. (Witness nodding.)

Q. You have to answer yes or no.

A. Yes. Sorry.

Q. Okay. So over the last few months, you've spent eight to ten hours preparing for the topics in the 30(b)(6) that you've been designated to testify on, correct?

A. And that would be in addition to the time that I spent in helping to provide the request for documents, interrogatories, et cetera.

Q. All right. Perfect.

So -- and then, of course, in addition to your knowledge, you've spent, I think, the last 15, 16 years at DDM as well, correct?

A. True.

Q. So if you would turn to page 6 of Briscoe 2. It's titled III, Subject Matter for Testimony.

Do you see that?

A. Yes, sir.

Q. And I want to go through -- we're going to do this in the second notice, but I want to go through this first notice in some detail, okay? So -- and it will also help us get our kind of lingo down between the two of us, all right?

So "a" is suspicious order monitoring systems. And I'm going to refer to those as the acronym SOM, suspicious order monitoring, okay?

A. Okay.

Q. And you're familiar and have spent time preparing today to be able to testify as to DDM's SOMS policy, correct?

A. Yes.

Q. And you're familiar under b with the -- a term of art in the -- with the DEA about Know Your Customer?

A. I am.

Q. All right. Would you explain what your understanding of Know Your Customer is.

A. So essentially anybody that is

distributing has a responsibility to ensure that those that they're distributing to -- in our instance, we don't have customers, but, rather, stores that are under our umbrella that we distribute to, that we have a familiarity with, in a formal way, to ensure that they have a DEA license that's active, and then also that we have the ability to know that their ongoing business practices, you know, are in good standing. So it's not just enough to have a valid DEA license. We also have to be operating in a -- in a manner that would give us confidence in distributing products to those entities.

Q. And so the customer, as referenced here in b and is known in the industry with DDM, is its own wholly-owned pharmacies, correct?

A. Yes.

Q. And c, "Your past/present interpretation, compliance, agreement and/or disagreement with the Dear Registrant letters from the DEA outlining the duties imposed on a distributor under federal law."

You're prepared to testify today

on behalf of DDM regarding its duties under federal law as a distributor, correct?

A. Yes.

Q. And you understand, sir, today that DDM is here in its capacity as a distributor to its own wholly-owned pharmacies, correct?

A. Yes.

Q. And you understand that its role as a distributor is different than its role and obligation as a pharmacy or dispensing operation, correct?

A. Yes.

Q. Under d, "Your past/present interpretation, compliance, agreement and/or disagreement with the reporting requirement and shipping requirement as referenced in Masters Pharmaceutical."

Are you familiar and prepared to testify today about the shipping requirement and the due diligence requirement under -- I'm sorry -- reporting requirement and shipping requirement as reported and referenced in Masters?

A. Yes.

Q. And (e), "DDM's interpretation and compliance with the reporting requirement and whether that's changed over time"?

A. Yes.

Q. F, "DDM's interpretation and compliance with the shipping requirement and whether that's changed over time"?

A. Yes.

Q. All right. Let's stop there for a second.

Would you explain to me what your understanding of -- "your" meaning DDM's -- interpretation is of the Masters reporting requirement.

A. So I could start -- is it okay if I start with how we operated pre Masters, or would you like me to start from my interpretation of --

Q. You just explain to me, for purposes right now of going through this list, of what the reporting requirement is.

A. So the reporting requirement, if you were to identify a suspicious order that

needs to be reported to the DEA.

Q. Okay. And then under g, historically whether you have shipped suspicious orders without reporting and/or conducting due diligence prior to Masters Pharmaceutical.

You're prepared to testify today to that issue, correct?

A. Yes, sir.

Q. All right. H, past/present policies and procedures related to due diligence once a suspicious order is detected.

Correct?

A. Mm-hmm.

Q. And i, your past/present policies, procedures, standards and metrics used to identify orders of unusual size, orders deviating substantially from a normal pattern, or orders of unusual frequency.

You're prepared to testify today on behalf of DDM in regard to the language I just read in subsection i?

A. Yes.

Q. All right. J, your policies, procedures, standards and metrics used to

identify suspicious orders and how those have changed over time?

A. Yes.

Q. And k, policies, procedures, standards and metrics used to set and/or alter thresholds.

Correct, sir?

A. Yes.

Q. And what those have changed over time, correct?

A. Mm-hmm.

Q. And the policies and procedures related to the DDM's responsibility to perform due diligence on suspicious orders, correct?

A. Yes, sir.

Q. And m, your past/present programs, policies and procedures relating to maintenance of effective controls against diversion, as required under the U.S. Code.

Correct?

A. Yes.

Q. You're prepared to testify on those topics?

A. Yes.

Q. And the very last one, o, whether or not any consultant or other third party retained to assist you in the maintenance of effective controls.

So whether DDM hired any third party or vendor and used any outside assistance in performing its obligations as required under the federal law and the regs promulgated thereunder, correct?

A. Are you asking if I'm prepared or would you like an answer?

Q. No, sir. Whether you're prepared.

A. Yes.

- - -

(DDM-Briscoe Exhibit 3 marked.)

- - -

BY MR. MOUGEY:

Q. Hand you what we've marked as Briscoe 3.

A. Thank you.

Q. All right. Briscoe 3 looks almost identical to Briscoe 2, excepting for some of the list of what you're being asked to testify today on behalf of DDM's changed just a bit.

I'm not going to go through these, but I'm -- is it -- are you prepared to testify on each and every one of these topics that you've been designated on under the 30(b)(6) notice, too?

A. Yes, sir, with the absence of Number 10, as we discussed.

Q. Yes, sir. The data mine?

A. Yes.

Q. And then there are other topics that were carved out, but --

A. Yes.

Q. -- other than 10 --

A. Yes, sir.

Q. -- and the topics that were previously carved out, which essentially is 6, 7, 8, 9, 11, 12, 13, all the way to topic 23, with the exception of 19?

A. Correct.

Q. Thank you.

MR. JOHNSON: A point of procedure.

(Discussion off the record.)

BY MR. MOUGEY:

Q. I have your -- what I believe is

your LinkedIn -- your resumé or your CV. I'll hand you what I've marked as Briscoe 4.

- - -

(DDM-Briscoe Exhibit 4 marked.)

- - -

(Discussion held off the record.)

Q. I've just put in front of you on -- as Briscoe 4 is what I believe is your CV.

Have you seen this document before?

A. Yes.

Q. All right. And when I say "your CV," I mean as it is on LinkedIn.

A. Yes, sir.

Q. And have you reviewed this document before?

A. Yes.

Q. Is the information accurate in Briscoe 4?

A. Yes.

Q. I just want to get a little bit of your background.

You have your PharmD from Northern University, correct?

A. Ohio Northern, yes.
Q. Ohio Northern.
And right out of school, you started with Discount Drug Mart?
A. I did.
Q. It was 2002, correct?
A. Yes, sir.
Q. And you've been in different capacities with Discount Drug Mart up until today, correct?
A. That's true.
Q. And started as a pharmacist and you were promoted in October of 2014 to -- as the director of pharmacy operations, correct?
A. Correct.
Q. After your initial role as a staff pharmacist, you were promoted to chief pharmacist in January 2006, correct?
A. Yes.
Q. And in May of '06, five months later, promoted to district pharmacy supervisor for Southwest Ohio, correct?
A. Yes.
Q. And in January 2008, about a year

and a half later, promoted to regional pharmacy supervisor for Central and Southwest Ohio, correct?

A. Yes, sir.

Q. And October '14 to today, you have been the director of pharmacy operations, correct?

A. Yes.

Q. Would you just explain to me your role from October '14 to now what is encompassed in pharmacy operations?

A. A little bit of -- of everything that we do related to our pharmacy. If you're familiar with Discount Drug Mart, about 50 percent of our business is on the front end and 50 percent is in -- in the pharmacy.

So part of my role as director of pharmacy operations would be a conduit to all the departments under the Discount Drug Mart umbrella, whether that's human resources, payroll, front end OTC procurement, our professional medical equipment and services business, our specialty pharmacy. So I'm kind of the quarterback, so to speak, between

interdepartmental communications.

Part of our pharmacy operations team, I report to a senior vice president of pharmacy. He has three directors, one of which is me, pharmacy operations. We have one that's pharmacy compliance and then also a clinical pharmacy -- a director of clinical services. And, again, kind of a -- as a right arm to the SVP of pharmacy, I play quarterback with those directors and the three additional pharmacy supervisors we have out in the field.

And then from there, our 74 retail locations, we have a responsible pharmacist, or what we call a chief pharmacist, at every location, and then no less than one staff pharmacist, depending upon the pharmacist staffing needs at those locations.

In addition to those pharmacists, we have what we call floaters, and they would be pharmacists that rotate from store to store, depending upon where the need is to cover shifts, which could be vacation-based, transitioning between a staff or a chief pharmacist at a location for a period of time.

And then in addition, we have PRN pharmacists.

So the number of pharmacists on our team that would essentially report upwards towards me would be roughly 225. And then out in the field we have roughly 700 technicians. So if you look at it from store level on the way up to pharmacy operations, everybody has a role to play, but if there are situations not resolved or questions not answered, they continue to float their way through --

Q. Okay.

A. -- to pharmacy operations.

Q. All right. Thank you.

Distribution centers. How many distribution centers does DDM have?

A. One.

Q. One. And has that been the same answer going back until 2000, say?

A. To my knowledge, yes.

Q. All right. And does that distribution center also distribute all of the controlled substances?

A. So let me back up a second.

When you mention distribution

center, are you speaking specific to the distribution of prescription medications?

Q. You tell me.

A. Okay. So we have a -- again, a front end operation that accounts for a large percentage of our business, where that distribution center fulfills OTC-related orders, but separate from that, but connected. And the way that we distribute via the trucks that are delivered to our stores would be our pharmacy distribution center, which, you know, we're here talking about today.

Q. And I'm not sure I'm following you and I apologize.

So when you say "OTC," what are you referring to?

A. From paper towels to motor oil to -- you name it.

Q. All right.

MR. JOHNSON: Over-the-counter.

A. We're a one-stop shop retailer from that perspective.

Q. Okay. So OTC stands for over-the-counter?

A. Yes.

Q. And when you reference OTC, you're referring to your -- your front end operations, which is all -- when you walk into the pharmacy, from candy bars to paper plates to --

A. Yes.

Q. -- whatever is in there?

A. Front end is a good term for it.

Q. All right. Thank you. And ...

All right. So what I'm referring to when I'm talking about distribution center is your -- your prescriptions, your -- whatever -- dosage units, pills, whatever --

A. Yep.

Q. -- how many --

MR. JOHNSON: And we can agree that that will stay the same unless you designate otherwise as we go forward?

MR. MOUGEY: Thank you. That would be helpful, yes. Thank you.

MR. JOHNSON: So we're all clear?

MR. MOUGEY: Thank you.

BY MR. MOUGEY:

Q. So distribution center for

prescriptions or more specifically for controlled substances, how many distribution centers for prescriptions or controlled substances does DDM have?

A. One.

Q. And where is that located?

A. 211 Commerce Drive, Medina, Ohio.

Q. Okay. And that one distribution center, is that different than the facility that carries all of the products for the front end of the store or the OTC?

A. Yes, sir.

Q. All right. And so all of the Schedule III, Schedule IV, Schedule V controlled substances that DDM distributes to its pharmacies come from 211 Commerce?

A. Yes.

Q. Now, did any of your roles in your 16-plus years at DDM cover responsibility for 211 Commerce, the distribution center?

A. As far as me being the responsible pharmacist on the license, no.

Q. Okay. Did you oversee the roles and responsibilities of DDM as a distributor in

any of your capacities at DDM?

A. The pharmacy manager reports to our SVP of pharmacy. However, I'm involved in supporting her if and when necessary.

Q. All right. We'll come back to that.

In part of your preparation for today, did you have an opportunity to review DDM's responsibilities under the Controlled Substances Act?

A. Yes.

Q. And you understand the Controlled Substances Act is the kind of rubric that governs --

A. Is that supposed to be blank?

Q. I should have explained that to you when we started. The screen in front of you, when we have a document open, it's a -- it's a little distracting. But it's the same document you have in front of you. And if I'm referring to a specific paragraph or a specific sentence, which we'll get there, it will help you kind of find where you are. But it's the same thing. So if you have a paper version, you

can feel free to use that. If you want to use the one on the screen, use that.

A. Got it.

Q. Okay? Sorry. I should have said that in the beginning.

A. Okay.

Q. So you understand that the Controlled Substances Act or the CSA governs DDM's responsibilities in its role as a distributor, correct?

A. Yes.

Q. And there are different or additional responsibilities that -- statutes that govern DDM's responsibility as a pharmacy, correct?

A. Yes.

Q. There is a rubric under the CSA that governs pharmacists in dispensing, and that is different than the roles and responsibility under the CSA for DDM as a distributor, correct?

A. Yes.

- - -

(DDM-Briscoe Exhibit 5 marked.)

- - -

BY MR. MOUGEY:

Q. I'll hand you what I've marked as Briscoe 5. I'll hand that to you for now.

A. Thank you.

Q. There's an additional exhibit sticker on this from another depo, so I just crossed that out and wrote 5 on there, okay?

A. Okay.

MR. JOHNSON: We can mark it ourselves.

MR. MOUGEY: Okay. I just didn't want you to get confused with the 6 on there.

BY MR. MOUGEY:

Q. So Briscoe 5 is a copy of the Controlled Substances Act, which -- do you have an understanding that that bill originated, as on page 2, in 1970 --

A. Okay.

Q. -- right in the middle of the page.

Do you see that?

A. Yes.

Q. All right. And I'd like to walk

you through a couple of -- of pieces of this -- of the Controlled Substances Act. And if you would please turn to -- there's numbers at the very top of the page in addition -- in addition to the Bates numbers at the bottom.

On the top of the page, upper right-hand corner, Number 5.

A. The number trailing MCK --

Q. Yes, sir, exactly.

A. Okay. Thank you.

Q. Thank you.

Under Title II: Control and Enforcement.

Do you see that?

A. Yes.

Q. All right. "The bill provides for control by the Justice Department of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal."

Do you see that, sir?

A. Mm-hmm.

MR. JOHNSON: Out loud.

A. Yes.

Q. Thanks. It's hard.

And, sir, if you would turn to page 8, which -- upper right-hand corner.

A. Here (indicating)?

Q. Yes. Second full paragraph that begins with "The bill." There you go.

"The bill is designed to improve the administration and regulation of the manufacturing, distribution, and dispensing of controlled substances by providing for a closed system of drug distribution for legitimate handlers of such drugs. Such a closed system should significantly reduce the widespread diversion of the drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control."

A. Okay.

Q. Let's start with just helping me understand what you believe some of these terms mean. So let's walk through the first three

words in the second sentence, manufacturing and distribution and dispensing, okay?

Explain to me what you understand a manufacturer, a distributor and dispensing is under the controlled system -- under the closed system. I'm sorry.

A. Okay. Manufacturing would be groups, entities responsible for bringing -- manufacturing, producing, bringing products to market that are approved by the FDA and the DEA with their specific schedule to be distributed, whether that be by wholesalers or an entity like ourselves, down to retail pharmacy or other dispensing locations.

Q. Now, DDM, in addition to distributing to itself, also used third parties on occasion for Schedule III, IV and V, correct?

A. So when you speak of DDM utilizing other sources, you mean our retail locations procuring product?

Q. Yes, sir. From -- when I say "product," I'm referring to Schedule -- Schedule III, IV, V, specifically here hydrocodone, okay?

So hydrocodone up until 2014,

Schedule III, correct?

A. Yes.

Q. All right. For hydrocodone DDM also secured the pills, whatever you want to call them, from other distributors other than the 211 Commerce -- the distribution center from DDM, correct?

A. Yes.

Q. For example, you all had agreements with Cardinal, correct?

A. Correct.

Q. You had agreements with PSI, correct?

A. Do you know the --

Q. I'm not trying to memory test. Just other vendors or other --

A. And McKesson, yes.

Q. All right. Now, you understand the difference between Schedule II and Schedule III under the Controlled Substances Act, correct?

A. Yes.

Q. Explain to me what your understanding of the difference between

Schedule II and Schedule III is.

A. The difference between Schedule II and Schedule III would be correlated to abuse potential or safety issues, whether it's the -- the FDA and DEA determining -- or the DEA determining what schedule that medication belongs in. And that could be a fluid process, as we've learned over the years.

But Schedule IIs compared to III, IVs and V need to be handled in a different manner within the closed system, in the manner by which you order them, in the manner by which you receive them, in the manner by which you keep records, in the manner by which you dispense them.

And the same goes for III through Vs, compared to a nonscheduled medication, in that if you think of it as in three buckets, each in our closed system have their own pathway that needs to be handled in a separate specific manner.

Q. So I like the description that you used, the abuse potential, meaning that Schedule II and Schedule III, the abuse

potential for Schedule II was -- was higher than, say, for instance, Schedule Vs, correct?

A. Generally speaking, yes.

Q. And Schedule II, DDM used other distributors in its procurement of those -- those Schedule IIs to dispense to its patients, correct, sir?

A. True statement. While IIIs through Vs, you know, we would have distributed to our stores. But also our stores would have had the ability to procure III through Vs from other means, as you provided the example of Cardinal.

It is only true that we would have procured Schedule IIs from the beginning of Discount Drug Mart's existence from entities outside of our own distribution center.

Q. Okay. Let's go back to page 8 of Briscoe 5 and the reference to a closed system.

What's your understanding of a closed system under the Controlled Substances Act?

A. My understanding would be that from start to finish, there is recordkeeping

and -- there's security measures along the way. There's recordkeeping along the way, so that at any part of the manufacturing, distribution, dispensing of that product, you would be able to point to every step of the way.

Q. Meaning that every -- every pill under the closed system under the CSA from manufacturer to a relabeler, wholesaler, or distributor to the pharmacy is tracked and monitored, correct?

A. I wouldn't commit to saying every pill. I would -- I would -- for example, if there was -- that would be tough for me to say that that would happen 100 percent of the time.

Q. That is the goal or objective, is that every pill is tracked from manufacturer to distributor, wholesaler to --

A. Sure.

Q. -- the --

A. Sure.

Q. -- pharmacy, correct?

And in order to be a participant in manufacturer, distributor, wholesaler and pharmacy, that entity has to be registered with

the federal government, correct?

A. Yes.

Q. And as a distributor, DDM is licensed by the federal government, correct?

A. We are.

Q. And in order to distribute even to your own pharmacies, DDM is required to follow the federal regulations for a distributor under the Controlled Substances Act, correct?

A. Yes, sir.

Q. Same document, sir, if you turn to page 34 under subsection 2. I want to direct your attention to the last part of that sentence, "The illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial detrimental effect on the public's health and general welfare."

So was DDM aware, going back to the initiation of this act, that controlled substances have a substantial detrimental effect on the public's health and the general welfare?

A. When -- when dispensed or when distributed in a illegal importation manner, is

that -- is that what the beginning --

Q. Yes.

A. Yes. Yes.

Q. And as you just mentioned that Schedule II and Schedule III, the abuse potential is significantly higher than it is for other types of prescriptions, correct?

A. Yes.

Q. And that was no secret going back to -- I mean, historically, going back decades and even hundreds of years, that there was significant abuse or potential for abuse with Schedule II and Schedule III opiates, correct, sir?

MR. JOHNSON: Objection.

Go ahead.

A. I was going to say that that would more likely be true if -- if this were not written in a legitimate way with corresponding responsibility by the pharmacy that would have dispensed it for legitimate medical purposes.

Q. So it becomes imperative that each of the participants in the closed system fulfill its responsibilities to minimize any potential

abuse for Schedule II/III opiates because they have or could have a substantial detrimental effect on the public's health and general welfare, correct?

A. Yes.

- - -

(DDM-Briscoe Exhibit 6 marked.)

- - -

A. I'm still looking this over.

Q. I hand you what I've marked as Briscoe 6. It's P-GEN-0064.

Now, what I've just put in front of you as Briscoe 6 is the regulations under the rubric of the Controlled Substances Act that include, amongst other things, the responsibilities of a distributor, okay?

A. Okay.

Q. Have you had an opportunity to review the applicable sections in this document that would apply to DDM's responsibilities?

A. When needed, yes.

Q. Okay.

A. I certainly know where I can access them when -- when needed.

Q. So I'm going to reference the actual page numbers of this document, and I'm going to take you to page 29, specifically subsection (e) at the bottom right-hand corner of that page that begins with "The administration."

Do you see that?

A. Yes, sir.

Q. All right. The administration may suspend any registration simultaneously with or at any time subsequent to the service upon the registrant of an order to show cause why such registrant [sic] in any case where he or she finds that it is an imminent danger to the public health or safety.

Okay?

A. Mm-hmm.

Q. And, sir, was DDM aware that through the 2000s into 2006, 2007, 2008, there were numerous DEA investigations into companies across the United States related to the distribution and diversion of Schedule II and Schedule III opiates?

A. I'm not sure. I wasn't there at

that time. My belief, being a pharmacist at store level, was, you know, yes, that's something we need to be aware of.

Q. And I understand the pharmacists at the store level. But what I'm referring to is DDM's responsibility as a distributor, okay?

Was DDM -- use the word "monitoring" -- developments in the -- with DEA's guidance --

A. Okay.

Q. -- and rules and regulations regarding the roles and responsibilities of distributors?

A. Yes.

Q. And were you aware, as we progress through the 2000s, 2006, 2007, 2008, that there were numerous suspensions or revocations of registrations for distributors related to suspicious order monitoring policies and procedures?

A. Honestly, I'm not sure.

Q. And if you'd turn to page 38 of this document. Specifically on the right-hand side of the middle of the page, section

1301.74 --

A. Okay.

Q. -- titled "Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs."

And do you see under (b) -- well, let's do (a) first. (a), "Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry with the administration or with the appropriate State controlled substances registration agency, if any, to determine that person is registered to possess the controlled substance."

So for DDM, DDM only distributed to it's wholly-owned pharmacies, correct?

A. Correct.

Q. So under (b), sir, is it your understanding that DDM was obligated to design and operate a system to disclose the registrant suspicious orders of controlled substances?

A. Yes.

Q. All right. And do you believe that DDM had a system at all periods of time at issue here --

MR. JOHNSON: Could we define those so that he knows?

Q. Well, let's do it this way:

From 1999 on, up to today, did DDM have a -- designed and operated a system to disclose to the registrant suspicious orders of controlled substances?

MR. JOHNSON: Objection.

A. I can speak from 2006 on, that, yes, we did. I'm not certain prior to that.

Q. 2006 on, you believe that DDM had a system designed to identify suspicious orders of controlled substances?

A. Yes, sir.

Q. And you believed that that system was designed to identify orders deviating substantially from the normal pattern and orders of unusual frequency?

A. Yes.

Q. Let's continue with that section, second sentence:

"The registrant shall inform the Field Diversion Office of the administration in his area of suspicious orders when discovered."

A. Yes.

Q. Do you agree that DDM had a responsibility to inform the DEA's field office in DDM's area of suspicious orders when discovered?

A. Yes.

Q. Now, the system that DDM created you believe identified orders of unusual size, orders deviating substantially from a normal pattern or orders of unusual frequency?

A. Yes.

Q. And was that an automated system, like a -- a computer-based model identifying those orders?

A. There were -- there are essentially three levels, one of which is automated, computer-generated. Second would be reviewed by pharmacy operations and, if necessary, the third phase would be due diligence. Beyond that, pharmacy operations review.

Q. And those three levels, automated, pharmacy, and due diligence, were in operation from 2006 until today?

A. Yes.

Q. And have they remained consistent or constant during that period of time?

A. Yes.

Q. Why don't you explain to me the -- what the automated system at -- at DDM was.

A. So there's essentially a couple -- well, not essentially. There are two reports, one of which is not specific to controlled substances, and even more specifically, not to opioids alone. But every purchase order our stores create will create a report that spits out -- and it's specific to an NDC or an item, so not a family of items.

But if that purchase order creates a level that is greater than the six-week average, then that would show up at store level, and that would show up in the distribution center as take a look because you've ordered a quantity that is greater than your six-week average. And, again, that is not specific to

opioids.

The second report is generated on a monthly basis, the first day of every month. The system will identify any controlled substances for which a location received at a quantity that is greater than the 12-month average, the 12-month monthly average of that item, and it would show up on a report that says this quantity this month has a -- is greater than the monthly average over the last 12 months.

And then from there, that report would be reviewed by pharmacy operations to determine if what invoked on that report can be explained prior to involving the store and following up with that store for due diligence.

And then our approach from there was if we did due diligence and the store responded in a manner that we were then satisfied, then that resolved that item that showed up on that report; therefore, that would not have been a suspicious order; therefore, we would not have reported it.

Q. All right. Let's break that down

into some different pieces for me --

A. Sure.

Q. -- okay?

So there's two reports. The first report you described was not specific to controlled substances. So explain to me what was included in that first report.

A. So our stores create purchase orders to be fulfilled by our distribution center. And typically on a weekly basis, stores send two purchase orders to be delivered once weekly at each location. And every item within that purchase order, possibly two purchase orders per week, that invoked a quantity greater than the six-week average, it's a take a look at store level. Do you really need this quantity? And it's also a mechanism for those at the distribution center to say -- or to capture fat finger errors. So if somebody intended to enter 1 but it came across as 11, it would be a way to prevent that purchase order from being -- ever even being processed. It would be a call back to the store to say, "Do you really need 11?" "Oh, no. Thanks for catching that error. Just

send me one."

Q. Let me stop you if I could. And what I'm trying to figure out -- and I'm sorry if I missed it, but I said what was included in that automated report. Is this front end to back end or is this just -- just --

A. Prescription --

Q. -- pharmaceuticals?

A. All --

Q. All pharmaceuticals?

A. All prescription items, regardless of scheduling.

Q. All right. So when you said "distribution center," you were -- you're just -- this report is --

A. Pharmacy.

Q. -- just covering pharmacy?

A. Yes.

Q. So it doesn't matter -- doesn't matter what pharmacy -- what pharmaceutical it was capturing in this report?

A. Yes, sir.

Q. All right. Six-week average. Six-week average of what?

A. Received items.

Q. All right.

A. So, for example, if a store ordered two -- let's just go over a six-week period.

If they ordered two bottles, then zero bottles, then two bottles, then zero bottles, then two bottles, that's essentially six bottles over a six-week period.

Q. Okay.

A. Therefore, their average is one bottle per week over that six-week period. But if they ordered two, this report would call that out as a potential anomaly that, "Hey, you're ordering a quantity that's greater than your six-week average." But that is not an anomaly that would be concerning to the store or to the distribution center in that example, based on that ordering pattern.

Q. So who would this -- what all do you call this report internally?

A. Greater than six-week average report.

MR. JOHNSON: Creative.

A. I can't take credit.

Q. And what department was responsible for reviewing that greater than six-week average report?

A. So the pharmacist who sent the purchase order would receive a copy. After they transmitted their order to the distribution center, we'd auto print a report that says, "Take a look," and then also those in the distribution center responsible for filling -- for fulfilling the purchase orders to be ultimately shipped back to the store.

Q. All right. So that report would go to, one, the pharmacist, and two, the distribution center.

And who was responsible, if there was an order in excess of the six-week average for performing any due diligence on that report or order?

A. It would be the pharmacy warehouse team.

Q. And when you say "the pharmacy warehouse team," what is -- who is that?

A. So it would be our pharmacy buyer

and those individuals that report and work with her. So in the example I've provided where there was a quantity of 11 and let's say it wasn't a fat finger, but it was, you know, "I'm raising my hand that we might need to take a look at this," that due diligence, if and when that would have occurred, would be forwarded from the pharmacy warehouse team to pharmacy operations.

Q. And you mentioned the pharmacy buyer being a -- you said -- you referenced "her." is that a specific individual that --

A. Yes.

Q. -- that filled -- who was that?

A. Jill Strang.

Q. Jill?

A. Strang, S-t-r-a-n-g.

Q. And how long was Ms. Strang in the role as pharmacy buyer?

A. As long as I've been there. I think further beyond that, too. I know that she's being deposed.

Q. Prior to 2006?

A. Yes, sir.

Q. All right. And would the only orders on that greater than six weeks average report be the orders that deviated from the average of that six weeks, or was it every single PO?

A. Every single PO that had any item, scheduled or otherwise, that deviated from that six-week average would be a -- would be on that -- on that purchase order.

Q. Okay. So would that be transmitted via e-mail to -- is it Stang?

MR. JOHNSON: Strang.

Q. Strang.

A. I believe it would have come across on their green bar report, similar to the reports that they receive when picking and invoicing their purchase orders.

Q. What is a green bar report?

A. That's just a description of the type of paper and report that's printed out that, you know, we use in our merchandising system.

Q. You mean that it's on green paper?

A. Yeah.

Q. All right. And what I'm trying to get to, is that -- is that a different report than the greater than six-week average report?

A. No.

Q. Is it a number of reports? Is it -- other than the six-week average report?

MR. JOHNSON: That is the six-week average report.

A. Yeah. Yes.

Q. So the green bar report and the six-week average report are -- are one and the same?

A. Yeah. And, again, I'm not positive that that copy that they receive is printed on green bar versus 8-1/2 by 11. I'm not -- I'm not sure about that.

Q. All right. And I apologize, you've already -- just keep walking through this.

So the greater than six-week average report comes to Ms. Strang. And what's the first thing she does with that report?

A. Her team would review it to see if there were anything that would jump off the page

that they need -- would need to raise -- raise their hand to somebody else.

Q. Okay. And is there a policy or procedure in place that set the criteria for what would cause Ms. Strang to perform due diligence on any order that was greater than the six-week average?

A. I don't believe so. That particular report -- I didn't mean to --

Q. No, that's okay.

A. -- rush the answer, but I don't believe so.

That report was not necessarily designated for the purpose of our SOMS, but augments it in a way that is potentially helpful at store level and in the distribution center. It's more of a report to create operational efficiencies in a way that we order all products.

Q. What it sounds to me like is it's more of an inventory management report, correct?

A. Yes.

Q. And the -- DDM's pharmacies, this was a way to ensure that there was not too much

product being delivered to the pharmacy for any of the -- any of the different prescriptions --

A. Yeah.

Q. -- so it was to create kind of a glut in the system, correct?

A. Yep. And we see value in that. If there's additional sets of eyes that are paying attention to a purchase order, unbeknownst to them or known to them, that we are seeing and providing you this information that you're ordering product greater than your six-week average -- which might not be actionable, which likely is not actionable -- it's value to us that they see it at the store and they would see it at the distribution center.

Q. All right. And you're familiar with the concept of just-in-time inventory, right? Money's -- inventory sitting on the shelves costs DDM money on its bottom line, right?

A. Mm-hmm.

Q. So the less inventory sitting on the shelf, the more money DDM makes, correct?

A. Inventory terms is -- is something that we -- we measure, right.

Q. So I believe what I just heard you testify was that -- that this report, this six -- greater than six-week average report, the specific purpose of that report was not to fulfill DDM's role or responsibilities under section 1301.74?

A. Correct.

MR. JOHNSON: Objection.

Q. All right. Let's continue with -- with Ms. Strang.

She decides that there's a -- an order that she wants to follow up with, correct?

A. (Witness nodding.)

Q. And --

MR. JOHNSON: You have to answer out loud.

Q. I'll keep going. I'll help too. And it's -- in typical conversation we do a lot of shaking head and saying "mm-hmm," and unfortunately, in order for everybody to get your testimony down, you have to say yes or no, okay? I'll let you know --

A. Let's get back to Jill Strang?
Q. Yes.
A. Yes.
Q. That really wasn't -- that was more of a statement probably with a little bit of inflection in my voice. That's my fault.
So let's get back to Ms. Strang, all right?
A. Yes, sir.
Q. Okay. So an order causes her, you said, to -- to raise her hand and she will potentially look at it further, correct?
A. Yes.
Q. All right. There's no written policies or guidance or anything for Ms. Strang to give her some parameters about what orders she should be following up on performing due diligence, correct?
A. That's true.
Q. And so do you have an understanding, sitting here today, of what the criteria Ms. Strang would use to follow up on an order?
A. Again, I think if it were a

significant anomaly, they would call the store and -- and "Hey, this came across as" -- and we're talking instead of 5, 50; instead of 1, 11. They would call the store and say, "This came across." And this, again, is not related specific to controlled substances, but could be. And then that would be the intervention before that purchase order had even been processed. So, therefore, it wouldn't be in motion to be fulfilled.

Q. It could be blood pressure medication, correct?

A. Yes.

Q. I mean, it could be acne medicine, right?

A. Right.

Q. I mean, it could be just about anything that there was an order that you called a significant anomaly would pop on that report, correct?

A. Yes.

Q. So you used the phrase "significant anomaly." So what is DDM's definition of what a significant anomaly was,

and under Controlled Substances Act, Schedule III Narcotics, what was the significant anomaly that would cause Ms. Strang to do further due diligence?

A. With that report?

Q. Yes.

A. That was not the -- the intent of that report. That report would kick out, to use my word, anomalies again where the average that they sent was greater than what they had received over the last six weeks. So there wouldn't be precision to that report kicking out items that are suspicious.

Q. So the purpose -- I'm sorry. Were you finished?

A. Yep.

Q. The purpose of that report, meaning the greater than six-week average report, was more of an inventory management tool, correct?

A. Sure.

MR. JOHNSON: I'll object.

A. But, again, we saw value in augmenting our other processes with sets of eyes

at the store and in the distribution center with that report.

Q. Okay. Let's get into your -- DDM's other processes, okay? And when I say "other processes," I'm still on Briscoe 6. I'm still under 1301.74, "DDM's responsibility for designing and operating a system to disclose to the registrant suspicious orders of controlled substances." Okay? So we just went over that -- that six-week average report.

What other reports or systems were in place from '06 on to identify suspicious orders?

A. Okay. There is a report that runs on a monthly basis, the first day of every month, and that -- and that report is specific to controlled substances. Again, we only carry Schedule III, IV, V, not Schedule II. And that report would identify families of items, such as -- a little more meaningful of a report than that six-week average because the six-week average spoke specifically to an NDC. And there are reasons why an average could have been lower with an NDC. If I switch manufacturers, then it

would stand to reason that the first time I order that product on a six-week report would invoke as an anomaly.

But back to the monthly report, that is identifying families. And by "families," I mean if drug X has five manufacturers, then there could be five NDCs associated with that drug X family that we would want to pay attention to related to movement.

So it would be more purposeful for us to track the purchase history by store, by family, to learn if that drug's family is invoking an anomaly that needs to be looked at by pharmacy operations. So I'll get back to the guts of the report.

It's any family that spits out a quantity ordered that month which was greater than the monthly average as calculated over the last 12 months. And this is at -- by store, by drug family, for all Schedule III through V products.

Q. All right. Monthly average, 12 months, by store, by drug family?

A. Yes, sir.

Q. And what was that called? What was that report called?

A. I think it's a controlled substance monitoring report.

Q. Okay.

A. I believe we defined it in the requests, but I -- I apologize. I don't know for sure.

Q. Okay. And the report was run monthly, correct?

A. Yes.

Q. And who did that report go to?

A. Tom Nameth.

Q. Tom Nameth? Joe's brother?

A. Spelled differently.

Q. Okay.

A. Maybe related.

Q. What's Tom Nameth's title?

A. He is now retired --

Q. Okay.

A. -- but at the time he was our director of pharmacy operations --

Q. Right.

A. -- from that period of time.

Q. And so did he retire in -- what year did he retire?

A. I know that about the time that I came into my role as director of pharmacy, he stayed on board in a part-time capacity. I don't have the exact month in front of me when he retired, but I believe it was maybe a year and a half later. So maybe early -- late '15, early '16.

MR. JOHNSON: He's on the schedule if that's what you're checking for.

Q. You started as director of pharmacy operations in October of 2014. So did Mr. Nameth receive those reports from '06 to whenever he retired --

A. Yes.

Q. -- in '14ish?

Yes? Okay.

MR. JOHNSON: Slow down. Let him get his whole question out. We're stomping on each other a little there.

Q. After he retired, he stayed in a kind of advisorial capacity for a while?

A. Yeah, he worked a couple of days a

week.

Q. Okay. Because he didn't want to spend too much time at home, right?

So let me make sure I don't have this confused. You filled his position when he retired. Am I mistaken?

A. You're not.

Q. Okay. So when he retired, did you assume responsibility for reviewing the controlled substance monitoring report?

A. Yes.

Q. All right. So sometime -- you began in October '14. Let's call it late '14, early '15, you assumed responsibility for reviewing the controlled substance monitoring report?

A. I would say it would be more close to when Tom fully retired, that that transition occurred specific to this report, which I believe to be late '15 or early '16.

Q. Okay. So he continued in that capacity until he totally phased out, which was late '15, early '16, somewhere in that ballpark?

A. I believe so, yes.

Q. Okay. So let's go back to the -- the guts of the report.

How was that delivered to either Mr. Nameth or yourself when it was generated on a monthly basis?

A. From -- our IT team created that report. I believe it was what we considered to be an auto job that automatically prints in -- ironically on green bar paper and then is delivered, typically by somebody on the pharmacy operations team, to Tom's desk and -- and now my desk.

Q. Okay. So it was delivered in a paper format?

A. Yes.

Q. And not via e-mail?

A. No.

Q. Okay. And were -- when those reports were given to Mr. Nameth, were they then kept or stored anywhere?

A. I don't know if the reports were retained in their entirety. I do know that he would sign off on at least the front page and retain -- and he would retain those. And each

of those reports are retrievable from that standpoint.

Q. What did -- once Mr. Nameth received the controlled substance monitoring reports with the monthly average going back 12 months by store, by drug family, what did he do with that report? What did DDM do with that report?

A. So looking by store, by family, we would look to see if that anomaly was one that could be explained in a way that did not -- that did not require due diligence involving feedback from the location that led to the anomaly.

For example, if we transitioned a particular drug family from a wholesaler into our pharmacy distribution center, there would not be 12 months of activity specific to the distributions of that drug family from our distribution center to that store. So for a period of time, it's possible there would be anomalies, to continue to use that word, that would be on that report that are completely understandable and -- and would not require additional steps which would then -- would have

involved due diligence with interaction with our store.

Q. All right. So each of the reports we've discussed so far, the six-week average report and the controlled substance monitoring report, were each generated once a month, correct?

A. The second report that we're speaking on right now, once per month.

Q. Once per month?

A. The first report was every purchase order at every store at the time the purchase order is created. And, generally speaking, our stores send two to three purchase orders to the distribution center on a weekly basis, but they receive just one shipment via our distribution channels on a weekly basis.

So the first report is anytime somebody creates an order directly from a store specific to prescription medications to our prescription distribution center.

Q. Okay. What was the software or database that each of those reports were generated out of?

A. I believe the computer software program is John II or John III. I know we utilize -- our merchandising system which interfaces with the distribution center is the AS/400.

Q. And that answer applies to both of the reports we discussed so far, the greater than six-week average and the controlled substance monitoring report?

A. Yes, sir.

Q. Okay. Any other reports or systems in place designed to meet the requirements of 1301.74, which is a system designed to identify suspicious orders of controlled substances?

A. Yes, sir.

Q. Okay. What else?

A. So once we get beyond pharmacy operations review in a way that explains what would have popped as an anomaly, if we review but determine "I can't explain that this anomaly is actually legitimate because there's activity at store level associated with prescriptions that should be dispensed."

So if there is something that we need to take a deeper look at, there is due diligence taken between pharmacy operations and the store from which that anomaly showed on the report, and that report would essentially explain to the store, "We recognize that this month for this drug family, you ordered a quantity of X, and this quantity of X is greater than your last 12-month monthly average. Please provide me information as to how these additional -- you know, or this -- this order is not suspicious or this order was for legitimate purposes."

Q. All right. One thing I'm a little confused with still is that -- so once we go beyond pharmacy operations, is Mr. Nameth in pharmacy operations?

A. Yes.

Q. Okay. And while that report is being generated on a monthly basis and while pharmacy operations is reviewing the anomalies in that report --

A. Tom?

Q. Right, or yourself.

A. Yes.

Q. -- that order is then shipped to the DDM pharmacy, correct, sir?

A. Those orders would have been shipped, yes, because that monthly report where there's a retrospective view of what had occurred in the previous month ...

MR. JOHNSON: Peter, when you get to a natural place to take a break, let's take a midmorning break.

MR. MOUGEY: Sure. That's perfect. I'm good now.

MR. JOHNSON: Is now fine?

MR. MOUGEY: Yep. That is fine.

THE VIDEOGRAPHER: Going off the record at 10:17 a.m.

(Recess taken.)

THE VIDEOGRAPHER: Back on record at 10:35 a.m.

BY MR. MOUGEY:

Q. Mr. Briscoe, we've gone through the --

A. Exhibit 6, sir?

Q. Yes, sir, still Exhibit 6.

We've gone through two reports, the six-week average report and the second monthly report, controlled substance monitoring report, I think. Does that name, controlled substance monitoring report, anywhere -- appear anywhere on that document?

A. I'm going by memory alone. I believe there is a header on that report, but I don't recall if it's the term that I provided to you earlier or a term we might have provided in our request for documents. I apologize.

Q. Do you know if those reports are stored in any hard drive, server, somebody's filing cabinet?

A. I know that the top page of the hard copy reports I sign off on and file away in the event that the DEA would come in and ask for -- you know, "Show me where you did your portion of your order monitoring." And I also believe -- and I think in, again, the requests or the interrogatories when we described this process, they are retrievable. So we could, if we needed to retrospectively --

Q. Go back and pull them --

A. Yes.

Q. -- on a monthly basis, going back to -- at least to 2006?

A. I can't speak with confidence on how far back we would be able to pull them, but I think the answer to that is yes.

Q. Okay.

MR. JOHNSON: Are they -- can I clarify? Are they in paper form or are they electronically stored someplace?

THE WITNESS: Well, part of my process whenever -- my segment of the overall puzzle, so to speak, I sign the first page and document that I've reviewed all item families at all stores, and then I sign that and store that page.

His follow-up, I believe --

MR. JOHNSON: Store it in paper?

THE WITNESS: Paper.

MR. JOHNSON: Okay.

THE WITNESS: Yeah. Wet ink signature.

MR. JOHNSON: Okay. So I just

want to clarify because I -- I have a feeling Peter is going to ask to see those or may want to.

Are they -- are they stored anywhere electronically?

THE WITNESS: The report themselves, I don't know that "stored" is the right word or able to be retrieved by generating the report on demand.

MR. JOHNSON: Oh. So we'd be generating a new report to simulate old reports?

THE WITNESS: Correct.

MR. JOHNSON: Okay.

BY MR. MOUGEY:

Q. I think what you testified to earlier is that you could repopulate the previous report through the system; is that --

A. Yes.

Q. All right. Outside of those two reports -- and I'm still on Briscoe 6, section 1301.74, identifying DDM's responsibilities as the distributor to have a

system designed to identify suspicious orders, okay?

What other systems were in place at DDM other than the two reports we just discussed designed to identify suspicious orders?

A. So the process by which Tom Nameth or myself would review by store, by item family, if we determined that any item family at any respective store could not be explained and required further review with the involvement of the store that was involved, we would send that store what we call a due diligence report outlining why they're receiving this document related to this month's activity associated with that family of drugs, and then requiring, requesting in an urgent manner reasons and/or data associated with what led to them ordering and receiving that quantity that month.

Q. Now, let's go back to the actual formula for what that report populated. That was a 12-month average by store, by drug family.

A. You got it.

Q. Okay. So what is the average?

What -- is it prescriptions? Is it dosage units? Is it MME? What is the average? Average of what?

A. It would be units of -- you know, whatever a unit would be of a stock package. So if it were a bottle of 100 tablets, it would -- again, so if there's a family that's involved, so a 100-count bottle versus 500-count bottle, it would -- it would expose to us the activity by NDC within the family. So we would have full view of all activity of any NDC associated with that family, so we could see if they received six bottles of a 100-count or one bottle of 500-count that would be tabulating towards that monthly average.

Q. All right. So is the tabulation to the monthly average dosage units?

A. Bottles.

Q. Okay. But a bottle could be just as you just indicated, 100 tablets or 500 tablets. So if it's just by bottles, you could have five bottles of 500 dosage units for 2,500 dosage units over one month and that would only be five bottles, or -- and then the -- the next

month you could have -- you know what? Strike that. Let me do it the other way.

You could have five bottles with 100 dosage units and -- for one month and that would be 500 dosage units, correct? Right?

A. Yeah. Yes.

Q. Okay. And then the next month you have five bottles again with 500 dosage units?

A. I'm tracking with you.

Q. Okay. So the 2,500 versus the five would be a 500 percent increase, correct?

A. In your example, yes.

Q. All right. Go ahead.

A. And that would be -- you know, the reason for our approach in not using that computer-generated or systems-generated report alone to precisely identify suspicious orders because that wouldn't be enough the way that that report is created.

So in your example, I would have a full view or Tom would have a full view of the example you just provided, and that would be a potential reason that that example is more likely to require the next level of the due

diligence report, rather than just relying on this report spitting out five bottles versus five bottles of the monthly average over 12 months. That's not good enough, and that's part of the reason why there's human involvement before that next step involving the store would be.

Q. How many DDM pharmacies in the State of Ohio, 70?

A. In Ohio?

Q. Yes.

A. Currently retail locations?

Q. Yes.

A. Seventy-four.

Q. Seventy-four. And that number has stayed fairly consistent over the last 10 or 15 years, correct?

A. We've had some pretty strong conservative growth where -- in 2006, I bet we were in the low 60s as far as store numbers.

Q. So 60, 70 pharmacies from 2006 to now?

A. Mm-hmm.

Q. And you asked me just Ohio. My

understanding is DDM just does business in Ohio. Am I mistaken?

A. And my question for you was just retail locations.

Q. Okay. But DDM only does business in Ohio, correct?

A. You got it. Yes.

Q. And the distribution center for the pharmaceuticals is in Ohio, correct?

A. Yes.

Q. And the pharmacies are all located in Ohio, correct?

A. Yes.

Q. All the organizational structure at the operational level is in Ohio?

A. Yes.

Q. All right. So -- now, the report, we -- that report, the average is just based on bottles?

A. But it provides granularity to what is leading to that number. So if you were to look at the report, it would provide any NDC and associated package size within a drug family.

Q. Right.

A. So if I -- if drug X had five NDCs but three of which that store purchased from our distribution center that month --

Q. Mm-hmm.

A. -- we would see all three NDCs in the associated package size and quantity.

Q. All right. So what would trigger a store -- an order being placed on that report exceeding that average? I mean 10 percent, 50 percent, 100 percent?

A. 99 percent greater than the monthly average when calculated over the last 12 months.

Q. So essentially it would have to double?

A. Yes.

Q. How many pages were those reports typically?

A. The way the green bar is printed -- I mean, if you're talking about number of sheets of paper --

Q. Yeah.

A. -- it would be one page for every

store followed by one blank page followed by the next store. So if there are 74 stores, 148 pages.

Q. All right. And how often would a -- frequency-wise would a store be on this report with an order that exceeded the previous 12-month average by bottle by 99 percent?

A. Tough for me to characterize your definition of "frequent." I mean, I would say very infrequent. I don't know how else to characterize that.

Q. Meaning that it was not very -- we can -- it was not a regular occurrence for an order to be on the suspicious order monitoring report because it exceeded the previous 12-month average by bottle by 99 percent?

A. Yeah. A large majority of the time, a large majority of our stores would have no instances by which a drug family would -- would populate on this report.

Q. Let's put it this way:

DDM did not have a significant part of anyone's responsibility designed to monitoring and reviewing that report on a -- on

a monthly basis because there really were not that many entries, correct?

A. Well --

MR. JOHNSON: Objection.

A. Yeah. I wouldn't say that we didn't take that report seriously or it wasn't reviewed in a significant manner. It certainly was. The report and the number of examples that would populate wouldn't -- does not take a terribly long time to work based on the infrequency by which a drug family populates.

Q. From 2006 until last Friday, DDM has never had an order from any of its pharmacies that it considered suspicious and, therefore, reported it to the DEA, correct?

MR. JOHNSON: Objection.

A. Yes.

Q. "Yes" meaning --

A. Correct.

Q. -- DDM has never reported one single order to the DEA as suspicious from 2006 until at least last Friday, correct?

A. That is my understanding, yes.

Q. Those two reports, pharmacy

operations, Mr. Nasmith (phonetic) --

MR. JOHNSON: Nameth.

Q. Thank you.

-- Nameth and -- basketball, football.

Those two reports, Mr. Nameth -- Ms. Strange, was it? Stange? Strange?

MR. JOHNSON: Strang.

MR. MOUGEY: Strang. Thank you.

BY MR. MOUGEY:

Q. Those two reports, Ms. Strang, Mr. Nameth, outside of that description, what else did DDM do to fulfill its responsibilities under 1301.74 to identify suspicious orders of controlled substances?

A. So it would be that -- that third phase where, once Mr. Nameth or myself would work that report, if we were to identify that followup was necessary, in our view, from the store, we would send that form that I've described as due diligence explaining why they're receiving the form based on that monthly report, and then with some instructions on what information they would need to provide back to

us, for us then to review their feedback on why that order was shipped at the quantity it was compared to the last 12 months, and then we would make a decision on whether that would be resolved or not.

Q. So from 2006 until -- well, it's almost a 13-year period -- based on these reports, due diligence analysis, the monthly analysis of the pharmacies under the controlled substance monitor policy report, the six-week average report, the follow-up on the due diligence, DDM never identified one single order as suspicious, despite the fact it shipped and distributed 72 million dosage units of hydrocodone in the State of Ohio, correct?

MR. JOHNSON: Objection.

A. Yeah, I can't speak to the dosage units accuracy, but I can tell you that we've not reported a suspicious order.

Q. Do you have any idea what kind of volume DDM has -- has distributed in the State of Ohio dosage unit-wise?

A. I know where I could grab that information, but off the top of my head, I do

not.

Q. Would 72 million dosage units in the State of Ohio from DDM surprise you from 2006 to 2014?

MR. JOHNSON: Objection.

Q. Hydrocodone?

MR. JOHNSON: Objection.

A. I would have to -- to -- again, would it surprise me? I'd have to look at other information associated with dosage units, associated all controlled substance or, further, all dosage units of all medications that we dispense to see what percentage of dosage units we dispense at our retail locations were opioid compared to the entire bucket. Forgive my term.

Q. Sir, did DDM have any part of the process you just described to me where it was monitoring Schedule IIs like OxyContin in conjunction with its own Schedule III distribution?

A. From a distribution standpoint, no.

Q. Okay. So 1301.74, the regs under the Controlled Substances Act, you would agree

with me that if DDM was shipping suspicious orders without performing due diligence, that those would be unlawful, correct?

MR. JOHNSON: Objection.

A. If those orders that had been shipped, following our review, we learned to have been resolved, then, no, I don't believe in our view in that period of time that we're discussing would have been unlawful.

Q. What I'm asking you is a little bit different. What I asked you was, under the Controlled Substances Act, that if DDM shipped suspicious orders without performing due diligence, those -- that would be unlawful, correct?

MR. JOHNSON: Objection. It's a hypothetical.

A. I don't believe we have been involved in any unlawful activity associated with the distribution of the products from our -- our distribution center.

Q. And I understand. What I'm asking you, though, is, today, you're here as a representative of DDM and your understanding of

DDM's obligations under the Controlled Substances Act, correct?

A. Yes, sir.

Q. And what I'm asking you is, if DDM shipped suspicious orders without performing due diligence on those orders, those shipments would be unlawful, correct?

MR. JOHNSON: Objection.

A. Again, you know -- prior to the Masters case, you know, my answer would remain the same -- and I think that would be industry standard -- that orders had been shipped, that there was due diligence done after the fact to learn that they were resolved.

Our situation is somewhat unique, in that we are all under one umbrella in a closed system, and literally a closed system, in that our distribution center is only shipping to our stores, and we have measures and steps and processes and recordkeeping associated with knowing that all the pharmacies that we're distributing to are practicing pharmacy the right way.

Now, post Masters and -- and the

way that that ruling came down -- and, again, there's some potential room for interpretation based on Masters and some of the factors associated with them specifically and the way the ruling came down, but on a go-forward, we will be looking to identify a suspicious order and prevent that from being shipped.

Q. The anomalies -- your word -- that were identified on the reports that you -- that DDM used, those were suspicious orders, correct?

A. No.

Q. And in order to be on those reports, DDM considered those orders the to be anomalies, right?

A. Yes.

Q. And anomaly is, in your terms, what, a rare occurrence?

A. No. It's something that deserves to be looked at further because the report -- or the reports themselves were not or are not created in a way that's precise enough to spit out what exactly is a suspicious order from the standpoint of it should be shipped or it shouldn't be shipped. So in both directions,

our system has value in somebody taking a look. So we had to start with what do we take a look at. And those are those anomalies that I speak of. But those are not viewed in our system as defined by -- you know, they're not suspicious orders.

Q. Are you familiar with the -- the term "red flag"?

A. Yes.

Q. Would you agree with me that the orders identified on the reports we just walked through were red flags?

MR. JOHNSON: Objection.

A. Again, the report in the way that it's designed is not precise enough to characterize those as red flags, because examples of us moving from an ordering behavior away from a wholesaler to our distribution center would create a situation by which that first bottle you receive is greater than your 12-month average because there was no activity from the distribution center on that example.

Another example would be that based on days' supply being dispensed in a

legitimate manner at our retail locations, the ordering patterns dictate two bottles January, no bottles February, two bottles March, et cetera, leading to a one-bottle average for that location in that drug family; therefore, six out of those 12 months, that item potentially would pop as an anomaly because 2 is a greater than 1 average -- that -- that 2 is greater than the average of 1. That is not suspicious upon review by Tom Nameth or myself in taking a look at dispensing history at that location to see that pattern.

Q. The reports which we just walked through were not precise enough to identify specific trends that warranted or dictated that there be human involvement reviewing those reports, correct?

A. The strength of our process, our suspicious ordering monitoring system, is the totality of its components, and the human factor is an important part of that.

Q. So not precise enough equates into a need for human involvement, and that translates to the totality of the circumstances?

A. So to the point where Tom Nameth or myself is latched onto the reports to review, and then we have a responsibility to then determine if there's further activity or further communication with the store for which that anomaly populated. So that would be the due diligence.

Q. So let me get this straight. The reports are not precise enough on a monthly basis that DDM has to have individuals reviewing those reports, correct?

A. Yeah. I'd probably characterize that in a negative manner, but, yeah -- yes.

Q. And while the human involvement is trying to figure out things like adding up dosage units and NDC codes and -- and putting more meat on the bones, so to speak, the orders are shipped, correct?

A. Yes.

Q. And when the anomalies are identified on these reports on a monthly basis that are not precise enough to warrant kind of manual calculations, those aren't reported to the DEA, correct?

MR. JOHNSON: Objection.

A. No.

Q. Meaning they're not reported to the DEA, so the answer to the question is yes, right?

A. Yeah, they're not reported to the DEA.

Q. That's right. So often, by the time the reports are generated, the information is not precise enough, you have to do some manual calculations, you continue to make phone calls and look at it further. By the time you get an answer back from the pharmacy, that order could be six, seven, eight weeks in the rearview mirror, correct?

MR. JOHNSON: Objection.

A. No, it would not -- that process would not be that lengthy in nature.

Q. If the order came out on -- came in on the 1st of -- just say 1st of January, okay, the report's generated once a month. So that 30-day window, the report's a month later, right? So there's one month after the order, correct?

A. Yes.

Q. So that order then is on that report as an anomaly, correct?

A. Yes.

Q. The calculations on the report aren't precise enough that warrant some human calculation, correct?

MR. JOHNSON: Objection.

A. Can you repeat that?

Q. The reporting, the data on the report, is not precise enough that warrants some human calculations, some adding, some math on the report, right?

MR. JOHNSON: Objection.

A. I think the intent of your question is that it's not precise enough to not warrant human interaction, meaning there needs to be human interaction?

Q. Sure. I mean, it's measuring bottles. You have to add up how many pills and how many dosage units are in each bottle. You've got to go and look through the 140-page reports and do some calculations to see what jumps, right?

A. And it's not -- you're characterizing it as a difficult process, but it's not.

Q. Sure. So that 140-page report, 30 days -- it could come out 30 days after the order was entered, right? So there's 30 days in the rearview mirror, correct?

A. Potentially, yes.

Q. You've got to go flip through the report, you've got to do some manual calculations, correct?

A. Yes.

Q. No one ever automated those calculations from 2006 until 2018 to make the calculations, just self-reporting, right?

A. Excuse me. I think those calculations, whether it's Discount Drug Mart or any entity, including the DEA, that's difficult to create something that is precise that you could treat as the truth without somebody taking a look at it.

Q. I'm not asking you that. What I'm simply asking you is, instead of bottle count, measuring dosage units could have been done with

a simple calculation, a simple formula within that report, correct?

MR. JOHNSON: Objection.

A. I think what you're suggesting is maybe the report could be enhanced that would make Tom's job or my job easier in normalizing the quantity that would have been received on a monthly basis.

Q. Sure. Because measuring bottle to bottle to bottle to bottle really isn't a -- comparing apples to apples, correct?

MR. JOHNSON: Objection.

A. It's exposed on the report, so the -- the extra layer is a little bit more work for those that are reviewing it.

Q. And over a 12-year period, no one ever thought at DDM to embed a simple formula, the NDC code with the number of dosage units in a bottle, so you could quickly see apples to apples, correct?

MR. JOHNSON: Objection.

A. I can't speak to if anybody thought about that or not. It certainly hasn't been implemented in a change. I could say

that's likely due to our past performance, in that we haven't had issues that would have had us take a longer look at the way that we're having this approach, again, in its totality.

Q. Sure. And you've never reported a suspicious order to the DEA as required under 1301.74 in 12 years, correct?

MR. JOHNSON: Objection.

A. Correct.

Q. So maybe saying "We're the gold standard and we've never had an issue," you recognize as DDM it's your responsibility to identify suspicious orders, and no one at DDM ever thought about embedding a simple formula translating bottle count into dosage units so the person reviewing the report could compare apples to apples, correct, sir?

MR. JOHNSON: Objection.

A. I wouldn't -- I mean, I didn't say we were the gold standard. I would say we have confidence in the way that we operate. And, again, I can't speak to if anybody thought about that. I would agree that that hasn't been changed since the time the report was first

created.

Q. And no one from DDM ever took the time to embed a simple formula translating bottle counts into dosage units so the individual reviewing that report could compare apples to apples, correct?

MR. JOHNSON: Objection. Asked and answered, I believe. Yeah.

Q. Please answer the question.

A. Yeah. Correct. And, again, I view that as it -- it would make the process of reviewing the report slightly easier for Tom Nameth or myself.

Q. Sir, if you'd turn to page 71.

A. Sure.

Q. We've already covered this generally. I just want to -- specifically on page 70, do you see the title Part 1306, Prescriptions?

A. I'm sorry.

Q. Page 70, bottom of the --

A. Seventy?

MR. JOHNSON: Lower left of 70.

Q. Seventy.

A. Yeah, I'm with you.

Q. Okay. Prescriptions in the lower left, okay, 1306?

A. Yes.

Q. And page 71, 1306.04, Purpose of Issue of Prescriptions.

Do you see that?

A. I do.

Q. And under (a), "A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice."

Correct?

A. Yes, sir.

Q. And it continues, The responsibility for the proper prescribing and dispensing of the prescribing practitioner [sic], but a corresponding responsibility rests with the pharmacist who fills the prescription.

Do you see that?

A. Mm-hmm.

Q. Did I read that correctly?

A. You did.

Q. Okay. And earlier we touched on the responsibilities of DDM as a pharmacy and the responsibilities of DDM as a distributor, okay?

A. Mm-hmm.

Q. And 1306.04 touches on the responsibilities of DDM as a pharmacy, correct?

A. Yes.

Q. 1301.74 that we went through on page 38 about a system designed to identify suspicious orders and reporting those suspicious orders, is DDM's responsibility as a distributor, correct?

A. Yes.

Q. And while those two may overlap, they are distinct responsibilities, correct?

A. Yes.

Q. Did DDM have any part of its system wherein it relied on data from its pharmacy operations to review suspicious orders from a distributor perspective?

MR. JOHNSON: Objection.

A. Yes. From the standpoint of the Tom Nameth and Jason Briscoe review post

anomaly, post report, and due diligence when involving the store. There would be information accessed, obtained, provided.

Q. So 1301.74 uses the word "system," designed a system, okay?

And what is the system that Mr. Nasmith used --

MR. JOHNSON: Nameth.

Q. I'm sorry.

-- Nameth used and yourself -- what was -- what was the system, meaning the written policies and procedures, to perform whatever due diligence or analysis on those reports?

A. There really wasn't depth to the written policy and procedure other than pharmacy operations to review.

Q. When you say there wasn't any depth, there really wasn't --

A. Well, in the procedure it mentions pharmacy operations to review.

Q. But that's it? So no depth meaning there's zero policies and procedures other than pharmacy operations to review,

correct?

MR. JOHNSON: Objection.

A. There's no examples to follow or details beyond that, yes.

Q. There's no examples, there's no criteria, there's no thresholds, there's no frequently asked questions. There is nothing other than pharmacy operations to review, correct?

A. And we're speaking at the distributor --

MR. JOHNSON: Objection.

A. -- distributor level?

Q. Yes, sir.

A. Yes.

Q. Yes, meaning there is zero criteria, zero thresholds, zero parameters? Anything of detail other than pharmacy operations to review, that's the entirety of the system with those reports, correct?

A. Well --

MR. JOHNSON: Objection.

A. -- I was speaking to the component by which Tom Nameth or myself would review. So

when you mentioned thresholds, in a sense, these reports are predicated on a threshold that we created to have these anomalies populate on a report to be reviewed. So I wouldn't agree with your entire statement within that question.

Q. Let's do it this way:

Once the anomaly is populated on the report, the entirety of DDM's system is for -- in writing is for pharmacy operations to review, correct?

A. Yes.

Q. So in writing, when pharmacy operations is reviewing the anomalies posted on those reports, there is no direction through criteria, thresholds, parameters, anything, to give pharmacy operations guidance when reviewing those anomalies, correct?

MR. JOHNSON: Objection.

A. Yes.

Q. Correct meaning there's nothing in writing, correct?

A. Correct.

Q. Okay. Now, sir, you're familiar that the DEA would provide information to

distributors, manufacturers, registrants in the system about what the requirements were under the regs, correct?

A. Yes.

Q. All right. And one of those examples -- let me hand you what I'm going to mark as Briscoe 7.

- - -

(DDM-Briscoe Exhibit 7 marked.)

- - -

BY MR. MOUGEY:

Q. What I've just put in front of you, Mr. Briscoe, is a letter from the U.S. Department of Justice, Drug Enforcement Administration, dated September 27, 2006, correct?

A. Yes.

Q. Now, have you ever seen this letter before?

A. I don't believe I have.

Q. Even preparing for today, have you ever seen it?

A. I don't believe I have.

Q. And dated on September 27, 2006,

the letter relays that it's being sent, in the very first paragraph, "to every commercial entity in the United States registered with the Drug Enforcement Administration to distribute controlled substances."

Correct?

A. Yes.

Q. "The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problems our nation currently faces." Okay?

Do you have an understanding, as DDM, whether or not it received this letter on or about September 27, 2006?

MR. JOHNSON: Objection.

A. Being that we would have been a DEA registrant, it would -- it would be my belief that, yes, we did.

Q. All right. And do you agree with the DEA that the responsibilities of -- strike that. Let me keep going.

Underneath Background --

A. Okay.

Q. -- "As each of you is undoubtedly aware, the abuse (nonmedical use) of controlled prescription drugs is a serious and growing health problem in this country."

Do you agree, sir, with the DEA in 2006 that the controlled prescription -- controlled prescription abuse is a serious and growing health problem in the country?

A. I wouldn't have any reason to disagree with what they cited.

Q. Was DDM aware in 2006 that the abuse of controlled substances was a growing health problem in the U.S.?

MR. JOHNSON: Objection.

A. I believe the answer would be yes.

Q. Was DDM aware in the State of Ohio that there was an opiate epidemic in 2006 of abuse of Schedule II and Schedule III?

A. I believe the answer would be yes.

MR. JOHNSON: Show an objection to that.

Q. The next paragraph, "The CSA" -- and that stands for the Controlled Substances Act -- "was designed by Congress to combat

diversion by providing for a closed system of drug distribution in which all legitimate handlers of controlled substances must obtain a DEA registration and, as a condition of maintaining such registration, must take reasonable steps to ensure that their registration is not being utilized as a source of diversion."

Did I read that right?

A. You did.

Q. And you agree with that sentence from the DEA, sir?

A. Sure. Yes.

Q. The next sentence, "Distributors are, of course, one of the key components of the distribution chain."

Do you see that, sir?

A. I do.

Q. And do you agree with the DEA that DDM, in its role as a distributor, is one of the key components of the distribution chain?

A. Yes.

Q. And, as the next sentence relays, "If the closed system is to function properly as

Congress envisioned, distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes."

Correct?

A. Yep.

Q. And your testimony today is that DDM had designed a system to identify suspicious orders that fulfilled its obligations to be vigilant?

A. Yes. And I think the highlighted portion speaks to vigilant in deciding whether a prospective customer can be trusted to deliver. And, you know, being that our stores -- being we don't have customers, but our stores are also operated under our umbrella, you know, is a strength from that perspective --

Q. Sure. As we talked about --

A. -- in knowing your customers.

Q. As we talked about a couple of hours ago at the very beginning, DDM's customers are its own pharmacies, correct?

A. Yes.

Q. All 60, 70 of them scattered

throughout the State of Ohio, correct?

A. Yes.

Q. And DDM's responsibility under the Controlled Substances Act in its role as a distributor is to be vigilant in identifying and reporting suspicious orders, correct, sir?

A. Not specific to this paragraph, but -- but, yes.

Q. And the last sentence of this paragraph, "This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people."

Do agree with that sentence?

A. I do.

Q. And you agree that DDM's role was critical in combating the opiate epidemic, not only in the State of Ohio, but beyond the state's borders?

A. I don't know that we would have had an -- a direct impact outside of Ohio, but I also want to point out that the background of this Dear Registrant letter, again, speaks to

vigilance associated with the distributor making sure it's only going to be shipping to -- excuse me -- customers trusted to deliver controlled substances only for lawful purposes.

And I do believe that we're vigilant in making sure that our stores are licensed by the DEA, in good standing, have ongoing business practices that would -- would meet the standards that they -- they mention -- or that they reference.

Q. And you have no question here today, sir, as DDM, that the responsibilities of DDM as a distributor were to have a system designed to identify suspicious orders, correct?

A. Correct.

Q. You have zero problem, zero equivocation with that statement? It doesn't matter if it's to your own pharmacies or not, DDM's role as a distributor was to design and implement an effective system to identify and report suspicious orders to the DEA, correct, sir?

MR. JOHNSON: Objection.

A. Yes, sir. But, again, not

specific to this Dear Registrant letter.

Q. This Dear Registrant --

A. Or at least that paragraph that we were on. Excuse me, sir.

Q. No, that's okay. Go ahead.

A. No, I'm done.

Q. The Dear Registrant letter that you're referencing here on September 27, 2006 was simply to reiterate those responsibilities, correct?

A. It appears to be, yes.

MR. JOHNSON: Objection.

Q. Right. And these responsibilities that we're talking about are not driven by this letter, but more from the Controlled Substances Act from 1970 we just looked at and the regs promulgated thereunder, correct?

A. Yes. And what I was trying to explain and I wasn't doing a good job is that -- and, again, I haven't seen this letter or don't have it memorized, so if we go down further and there's a section related to developing a process in place to prevent and report suspicious orders, then I apologize.

But, again, to me, the purpose of this letter appears to be making sure we're doing our due diligence and being vigilant and that who we plan to ship to, you know -- again, sorry -- can be trusted to deliver controlled substances for only lawful purposes.

Q. Right. And that the prescriptions that are going out the door of Schedule III are legitimate prescriptions for medical use, correct?

A. Yes, sir.

MR. JOHNSON: Objection.

Q. You're familiar with the term "diversion."

Correct?

A. Yes.

Q. Are you familiar with the concept of doctor shopping?

A. Yes.

Q. And DDM's role -- well, explain to me what doctor -- what your understanding of what doctor shopping is.

A. You know, it would be a situation by which a -- a patient is seeking a medication

from multiple prescribers.

Q. And either -- and those pills that were secured from doctor shopping have a high probability of being used for nonmedical use, correct?

A. Likely, yes.

Q. Yes. In that they would enter the stream of commerce through a -- an individual doctor shopping by selling those pills on the street, correct?

A. Yes.

Q. And DDM's responsibility --

A. I can't speak to what they would do with them on the street.

Q. Sure, but that -- you knew that was a problem. DDM knew that it was a problem with hydrocodone being sold on the street in the black market by nothing more than drug dealers after securing those pills from pharmacies in the State of Ohio, correct?

MR. JOHNSON: Objection.

A. Can you repeat that. I apologize.

Q. DDM knew that there was a problem in the State of Ohio with individuals doctor

shopping and then securing prescriptions and selling those pills on the street for nonmedical purposes, right?

MR. JOHNSON: Objection.

A. Yes.

Q. And those are drug dealers, right?

A. Sure.

Q. And they -- part of the way pills made it into the black market through drug dealers was securing prescriptions from doctors through a practice we just discussed as doctor shopping, right?

MR. JOHNSON: Objection.

A. Yes.

Q. And those were -- that is one example of many of ways that pills make it into the black market or into the street, correct?

A. That is one way, yes.

Q. And DDM's responsibility as a distributor was to be vigilant in designing a system that would identify suspicious orders and prevent pills like hydrocodone making it into this black market, correct?

A. We would need -- yeah, we

certainly are responsible for creating a system that would prevent medication, controlled substances, being shipped to our retail locations that ultimately was not dispensed for a legitimate medical purpose.

Q. If you go to the second page of this -- of Briscoe 7, the reiteration of responsibilities by the Department of Justice and the DEA, second paragraph.

A. I'm sorry. Where are we at, Exhibit 7?

Q. Exhibit 7, second page.

A. Okay.

Q. Second paragraph, the sentence that begins with "Moreover."

A. Okay.

Q. "Moreover, all registrants, manufacturers, distributors" --

A. Where are we?

MR. JOHNSON: I'm sorry.

Q. Do you see it?

A. Second sentence, second paragraph?

Q. Second sentence, second paragraph.

MR. JOHNSON: Oh, second sentence.

A. I'm with you.

Q. It begins with "Moreover." It's on the screen. Do you see that?

All right. "Moreover, all registrants, manufacturers, distributors, pharmacies, and practitioners share responsibility for maintaining appropriate safeguards against diversion."

Correct?

A. Yes.

Q. And you see there, this letter from the Department of Justice, that there is a separate entry for distributors and pharmacies, correct?

A. It's not highlighted. Okay, yeah, I see. Yes.

Q. They're separate.

A. I'm with you.

Q. One is distributor, one is a pharmacy, right?

A. I was looking at a different sentence.

Q. Right. So having a set of rules for pharmacists doesn't fulfill DDM's

responsibilities as a distributor in the State of Ohio under the Controlled Substances Act, correct?

MR. JOHNSON: Objection.

A. Ensuring that the pharmacies we ship to have a set of rules that lead to dispensing medications under the guise of a legitimate -- legitimate medical reason would be a reason or an avenue to ensure that we are being vigilant in knowing our customers and knowing who we are shipping to.

Q. But the question I asked you was a little different. I said, "Having a set of rules for pharmacists doesn't fulfill DDM's responsibility as a distributor under the Controlled Substances Act."

Correct?

A. No --

MR. JOHNSON: Objection.

A. -- it does not.

Q. Okay. Thank you.

The next sentence, "Nonetheless, given the extent of prescription drug abuse in the United States, along with the dangerous and

potentially lethal consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm."

Correct? Did I read that right?

A. You did.

Q. And, sir, you, as DDM, understood that in 2006, the DEA believed that controlled substances were dangerous and could have potentially lethal consequences, correct?

A. Yes.

Q. And you understood in 2006 and the years thereafter that the death rates in Ohio from overdoses continued to climb, correct?

A. Yes.

MR. JOHNSON: Objection.

Q. You understood that it was becoming, as you went through the 2000s, a national epidemic with overdoses and overdose deaths, correct?

MR. JOHNSON: Objection.

A. Yes.

Q. The next paragraph, "The statutory factors DEA must consider in whether to revoke a

distributor's registration are set forth in 21 U.S.C. 823(e). Listed among these factors is the duty of the distributors to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels."

Correct?

A. Yes.

Q. It's crystal clear from this 2006 letter that the DEA, through the Department of Justice, thought it was extremely important, critical, that distributors fulfill its role to implement a system to identify suspicious orders, correct?

MR. JOHNSON: Objection.

A. Maintain effective controls against diversion of controlled substances, so yes.

Q. It was critical?

MR. JOHNSON: Objection.

A. Their words or my opinion?

Q. A simple question. It doesn't matter whose words or your opinion.

It was critical that DDM design

and implement a system to identify and report suspicious orders?

A. It was their regulation, which we would, you know, take seriously and adhere to, yes.

Q. The DEA reiterates in the paragraph below that, the 1301.74(b), with the reg that we just looked through, reiterating that it's extremely important for DDM to have a system designed to identify suspicious orders, correct?

MR. JOHNSON: Objection.

A. How did you characterize --

Q. Just a reminder, another reiteration from the DEA --

A. Yes.

Q. -- quoting to 1301.74, correct?

A. Reiteration, yes.

MR. JOHNSON: Objection.

Q. Skip a paragraph. "Thus, in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into

other than legitimate, medical, scientific, and industrial channels."

Did I read that right?

A. You did.

Q. All right. Let's stop and focus on that sentence for a minute.

So in addition to reporting suspicious orders -- that's reiteration from the DEA Number 1.

Do you see that in that sentence?

A. If an order had been deemed suspicious, it's required to report, yes.

Q. A distributor has a statutory responsibility to exercise due diligence to avoid filling that order?

A. It said to avoid filling suspicious orders.

Q. Yes, sir. DDM filled the orders as they came in, whether it was identified as an anomaly on a subsequent report or not, correct?

MR. JOHNSON: Objection.

A. With the exception of the six-week average report that could have led to an error, that would have prevented that order from ever

being processed.

Q. The inventory management system?

A. Yes.

Q. Other than that, can you point me to one order at DDM from 2006 until today that was not filled, despite the fact it appeared as an anomaly on the controlled monitor -- monitoring system report that we discussed earlier?

MR. JOHNSON: Objection.

A. My answer is I don't believe that I could; however, I don't know that if there were a situation by which an order was not sent but yet populated in that report as if it was received, that would be one example where -- that would -- that would be something I -- I don't know for 100 percent certainty. But I don't know of any documented examples of what you described.

Q. So DDM would fill orders, populate a report subsequently as an anomaly, and then perform due diligence, correct?

A. We would first do the Tom Nameth/Jason Briscoe review, and then, if it

warranted due diligence, due diligence would follow, yes.

Q. And that process that you just described does not comply with the DEA's direction in the September 27, 2006 correspondence that a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders, correct?

MR. JOHNSON: Objection.

A. While you might describe our process as potentially leading to an order that would have been filled that shouldn't have because it would have been deemed suspicious, we've never had a suspicious order in the time frame that we are looking at.

Q. All right. Please keep that --

A. 7?

Q. -- 7 in front of you.

A. Sure.

- - -

(DDM-Briscoe Exhibit 8 marked.)

- - -

Q. And I'm going to hand you

Briscoe 8, which is reference number 00051.

A. What time do we have?

Q. A half an hour to lunch.

A. Okay.

Q. Hand you Briscoe 8.

A. I have it.

Q. Take a minute, if you would, sir, and compare -- well, let's do this:

Briscoe 8 is U.S. Department of Justice, Drug Enforcement Administration, dated December 27, 2007, correct?

A. It is.

Q. And that's approximately -- what is that? -- 14, 15 months after the letter we just reviewed, Briscoe 7, correct?

A. Yes.

Q. And take a minute, but these two letters appear to be almost identical, correct?

A. Yes. I'm slightly confused by the --

MR. JOHNSON: Well, we'll take your representation. Do you want him to read the whole -- the whole -- the letters?

MR. MOUGEY: It's a page and a half. I don't want anybody to take my representation.

BY MR. MOUGEY:

Q. The message in the September 2006 letter and the December 2007 letter, Briscoe 7 and 8, the messaging from the Department of Justice is -- is very similar, correct?

A. I'm not -- I'm not familiar with the letter. I may have read it in the past. I don't believe that I have, but I certainly wouldn't be able to attest that this letter is similar to the previous one, and I'm slightly confused why the header would include McKesson Corporation.

Q. It's because you all haven't produced this letter, so I used the example from McKesson.

A. Thank you.

Q. It's the same entry -- let's just go ahead and review the letter. And the letter is being sent to every entity in the U.S. registered with the Drug Enforcement Administration to manufacture or distribute

controlled substances.

Do you see that?

A. Yes, sir.

Q. Same entry as the previous letter, correct? We're sending it to everybody licensed in the closed system, correct?

A. Yes. Sorry.

Q. And that would be DDM. That would include DDM, correct?

A. Yes. At that time, yes.

Q. Yes. "The purpose of this letter is to reiterate the responsibility of controlled substance manufacturers and distributors to inform DEA of suspicious orders, in accordance with 21 CFR 1301.74."

Correct?

A. Yes.

Q. Very similar message to what came out in September of 2006, correct?

A. That paragraph, yes. Again, I'm -- I apologize. I'm not familiar with the guts of the rest of the letter yet.

Q. That's okay. We're going to keep walking through it.

The second paragraph walks the recipient through the requirement to report suspicious orders of controlled substance under 1301.74, correct?

A. Yes.

Q. And that paragraph continues, "Title 121 CFR 1301.74(b) specifically requires that a registrant design and operate a system to disclose to the registrant suspicious orders of controlled substances. The regulation clearly indicates that it is the sole responsibility of the registrant to design and operate such a system."

Correct?

A. Yes.

Q. All right. The DEA, through the Department of Justice, is reiterating the responsibility of DDM to design and operate a system identified to identify suspicious orders, correct?

A. Yes, sir.

Q. The next paragraph, Once those suspicious orders are identified, the DEA is relaying that they needed to be relayed to the

DEA when discovered.

Correct?

A. Help me with the highlight. I'm sorry.

Q. "The regulation also requires that the registrant inform the local DEA division office of suspicious orders when discovered by the registrant."

Do you see that?

A. Yes. I was getting spoiled. I'm sorry.

Q. That's all right.

Do you know where the local DEA office is in this -- offices are in the State of Ohio?

A. Off the top of my head, I believe there's one in Cincinnati, Columbus, and Cleveland.

Q. All right. If you had to report a suspicious order to one of the DEA field offices, would you know how to do it?

A. Yes.

Q. How would you do it?

A. We would provide formal

notification in a written manner. I believe they prefer fax of the suspicious order.

Q. The paragraph continues, the next sentence, "Filing a monthly report of completed transactions, excessive purchase report or high unit purchases, does not meet the regulatory requirement to report suspicious orders."

Do you see that?

A. Yes.

Q. Now, did anyone from DDM when receiving this letter inquire with the DEA what it meant by "excessive purchase report" or "high unit purchases"?

MR. JOHNSON: Objection.

A. I don't know if anybody reached out for clarification associated with excessive purchase report or high unit purchases.

Q. "Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an independent analysis of suspicious orders prior to completing a sale."

Do you see that?

A. Yes.

Q. But that's not what DDM did, correct? DDM would perform the due diligence after completing the order, correct?

MR. JOHNSON: Objection.

A. If there were a suspicious order, your statement would be true, but we've not had any suspicious orders.

Q. That's right. We've established that. In 12 years, DDM has never had one suspicious order that it ever thought was important to report to the DEA, right? We're on the same page, right?

A. We are.

Q. What I'm asking you is, before even -- any due diligence, that order appearing as an anomaly on one of your reports, you all, DDM, filled or completed that sale, and then determined whether it was suspicious afterwards, correct?

A. And I don't mean to --

MR. JOHNSON: Objection.

A. -- you know, latch onto the verb you're using, but it wouldn't have been a sale.

It would have just been a distribution to one of our stores, since they're not our customers and it's not a transaction by which we are creating revenue. It's just distribution. But --

Q. Let's use the word "order," okay?

A. Okay.

Q. Order, sale, DEA --

A. Can you repeat -- I got off track.

Q. That's okay.

So DDM is not determining whether an order is -- it's an anomaly, it appears in that report -- whether it's suspicious or not until after it completes the order, correct?

MR. JOHNSON: Objection.

A. The realtime opportunity to identify an order to be an anomaly that potentially would lead to due diligence and identified as an unresolved suspicious order would be based on that -- that inventory management report that every purchase order, regardless of schedule -- when that's created.

But the second phase of our system is a retrospective analysis of the previous month's purchases.

Q. Let's go back to that inventory management report, the six-week average, right, with -- is it Ms. Strang? Am I saying that right?

A. You got it.

Q. Okay. Thanks.

Ms. Strang, she would call the pharmacy, right, if she got -- something popped up on that six-week average report?

A. Whether it's blood pressure or --

Q. Yep.

A. Yep.

Q. I mean, it doesn't matter. The blood pressure, acne medicine, birth control, it doesn't make any difference what it is, right? She'd call the pharmacy and say, "You've popped up on my six-week average report."

Right? She was confirming that that order was placed and there was no fat fingers or anything, right?

A. True.

Q. There was no due diligence at that point other than confirming there were no fat finger entries on the keyboard, correct?

MR. JOHNSON: Objection.

A. It depends on how you're defining "due diligence," but I would think that that extra set of eyes in both the pharmacy and at the distribution center would be a layer of protection.

Q. If the pharmacist said, "Yes, I ordered seven bottles of some prescription acne medication," then it would get -- the order would go through, correct?

MR. JOHNSON: Objection.

A. I can't put myself in Jill's shoes. Depending upon the store, the medication, the situation, the answer, you know, Jill might have come to us to say, "We need to take a further look."

Q. I'm not asking you to be in Jill's shoes. I'm asking you from DDM's perspective. If DDM has a six-week average report, contacts the pharmacist and said, "This purchase order has popped up on my six-week average report. Did you, in fact, order seven bottles of this acne medication," and the pharmacist says, "Why, yes, we did," it would get shipped, correct?

MR. JOHNSON: Objection.

A. Depends, again, on Jill's interaction at -- with that particular conversation, but, you know, it --

Q. Let's call that the fat finger report. She's calling to check to make sure that the entry wasn't incorrect --

MR. JOHNSON: Objection.

Q. -- correct?

A. That's the initiation of her call, yes.

Q. Yes, sir. That report is simply checking to make sure that the purchase order matches what the pharmacist intended to enter, correct?

A. Yes.

Q. And if DDM calls and certifies and the pharmacy says, "Yes, that's what I intended to order," boom, it was -- it was sent out, correct?

MR. JOHNSON: Objection.

A. Possibly, yes.

Q. Okay. Well, when you say "possibly," what other -- what other policies

and procedures in the six-week average report, as the DDM representative here today, were in place in that specific six-week average report?

A. That's a slightly different question. I can't speak to policies and procedures that would give her next steps. But at the same time, I also can't agree that just because the pharmacist said "Yes, I want it," she would then send it.

Q. Sitting here today, preparing for your 30(b)(6) topics, asking you as the DDM representative to testify to what the policies and procedures were under the SOMS for DDM, are you aware of anything in writing that Ms. Strang, getting the six-week average report, would contact the pharmacy to confirm the purchase order -- is there anything else in writing other than that?

A. I would have to refer to our warehouse manual or our VAWD accreditation policies and procedures to answer accurately. I don't know that off the top of my head, if there is or there isn't written policy specific to those types of situations.

Q. Well, your testimony this morning was that there were two kind of umbrella reports, a six-week average and the controlled substance monitoring report.

So the six-week average report, in your preparation for today, you can point me to absolutely nothing in writing giving criteria, thresholds, parameters, for when Ms. Strang confirms the purchase order, pharmacist says yes, whether there's anything else she needs to check for?

MR. JOHNSON: Objection.

A. Again, I'm trying to be, you know, obviously accurate, you know, in my answer to you. I don't know for certain if we have written policies and procedures, but I know I would know where to look and where they're accessible for me to answer that question.

Q. But in your preparation for today that you've had a couple of months to work on, you have two reports, you don't know if there's anything in writing sitting here right now?

MR. JOHNSON: Objection. He already identified something in writing.

Q. Six-week average report, parameters, controls, thresholds, other than confirming the fat finger problem, you can't point to anything else in writing, correct?

MR. JOHNSON: Objection.

A. As I sit here right now, I can tell you that I've not memorized all of our policies and procedures within our distribution center's operating manual, and so ...

Q. And I'm not asking you, sir, if you've memorized them. Okay? What I'm asking is, sitting here today, after having months to prepare for this testimony, which is driven almost exclusively to suspicious order monitoring policies and procedures, out of the two reports, you can't point me to anything, not one single piece of criteria that Ms. Strang employs when contacting the pharmacist to confirm a problem with a fat finger entry, correct?

A. Verbally --

MR. JOHNSON: Objection.

A. Verbally as I speak here -- as I sit here now, I cannot.

Q. Okay. Let's go back to Briscoe 8, the sentence we were just on "... which registrants must conduct an independent analysis of suspicious orders prior to completing a sale."

MR. JOHNSON: Is that a question?

Q. Oh, I'm just making sure -- are you there?

A. "Registrants must conduct an independent" --

Q. Yes.

A. Yes.

Q. Explain to me what system DDM had in place to identify suspicious orders before they were shipped.

MR. JOHNSON: Objection; asked and answered.

But go ahead.

A. Again, it's the totality of our operation from a distribution standpoint, and knowing who our customers are, and access to the activity that occurs, and checks and balances, and reporting.

Q. Those are all very general

30,000-foot.

You understand -- you've testified repeatedly that DDM has a responsibility to identify suspicious orders, right? We've gone through what the systems are.

Prior to being shipped, what system does DDM have in place to identify suspicious orders prior to being shipped?

MR. JOHNSON: Objection.

A. Again, I would point to that -- the report that we just spent some time.

Q. The fat finger report?

A. The six-week average report.

MR. JOHNSON: Objection.

Q. So other than -- other than confirming whether the purchase order is correct from Ms. Strang to the pharmacist, is there any system in place that DDM has to identify suspicious orders before they were shipped?

A. No.

Q. All right. Let's turn the page for me.

MR. JOHNSON: Exhibit 8?

MR. MOUGEY: Exhibit 8. Thank

you.

Q. Now, would you agree with me that both of the reports you just identified, the six-week average and the controlled substance order monitoring report, are both based on rigid formulas?

MR. JOHNSON: Objection.

A. Would I agree that they're both based on rigid --

Q. Rigid formulas.

A. No.

Q. Both of those reports, in order to populate -- let me do it this way:

The orders that populate those reports are both based on formulas, correct?

A. Yes.

Q. And both of those formulas are rigid, correct?

A. "Rigid" meaning they're not fluid, and they're not dynamic, and they're changing on a regular basis?

Q. Yes.

A. That's correct.

Q. There's no statistical analysis

that goes into either that -- a report that's identified as an anomaly populating those reports, correct?

A. No.

Q. It's essentially one's a six-week average and one's a 52-week average, right?

A. Yes.

Q. All right. One's based on bottles and the other is a confirmation of the purchase order, right?

A. With the bottles, that's what -- the column that would -- the math is done on, yes. But, again, there's granularity to all NDCs within that family that would be displayed with detail on that report.

Q. So on the second page of Briscoe 8, the DEA relays in 2007 that "Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to defect suspicious orders."

Did I read that right?

A. You did.

Q. "For example, a system that identifies an order as suspicious only if the

total amount of a controlled substance ordered during one month exceeds the amount ordered by the previous month by a certain percentage or more is insufficient."

Do you see that?

A. Yes.

Q. So as of 2007, the DEA is telling registrants like DDM that comparing one month to the next based on a certain percentage is insufficient, correct?

A. Yes.

Q. And DDM continued to use that formula comparing orders to previous months despite the DEA's edict in this letter, correct?

MR. JOHNSON: Objection.

A. They were only components of our SOMS, in that this report we recognized was not precise enough -- I believe my words -- to have it stand on its face. So, therefore, the strength of our process involved the Tom Nameth and Jason Briscoe review followed by due diligence with the store, if necessary.

Q. But we just went through the fact that neither of the policies that -- none of the

policies that we've walked through identified orders as suspicious before they were shipped, correct?

MR. JOHNSON: Objection.

Q. That's problem number one, right?

MR. JOHNSON: Objection.

A. There weren't any orders that were suspicious, but in a hypothetical ...

Q. No, I'm not -- this isn't a hypothetical. You didn't identify one order in 12 years, DDM, that was ever suspicious. So this isn't a hypothetical.

In 12 years that we're talking about, '06, to 2018, DDM used a formula to compare one month's orders to previous orders, correct?

A. We did, yes.

Q. And one of those formulas was simply to confirm purchase orders with the pharmacist, correct?

MR. JOHNSON: Objection.

A. One of the two reports?

Q. Yes, sir.

A. Yes.

Q. Neither of the two reports were designed to halt or cease shipments once that anomaly -- that order was placed on a report, correct?

MR. JOHNSON: Objection.

A. On their face --

Q. Yes.

A. -- by themselves?

No.

Q. Once -- even though it would populate a report, the order would still go out the door, correct?

A. Yes.

Q. Even though it would have been identified as an anomaly on that report, correct?

MR. JOHNSON: Objection.

A. Yes.

Q. The DEA relayed that formulas comparing one month to a next are insufficient to identify suspicious orders, correct?

MR. JOHNSON: Objection.

A. Yes.

Q. And that was DDM's system to

generate -- the only -- only reports it generated were both based on formulas comparing month to month, correct?

MR. JOHNSON: Objection.

A. That is correct; however, that was not the end of the system. That was only the first portion of our system.

Q. But the only anomalies that were reviewed by Mr. Nameth, DDM, anyone at DDM, were anomalies on those reports, right?

MR. JOHNSON: Objection.

A. The only anomalies that would have been investigated specific to these reports, yes. If there was another situation that was brought to our attention, I can't speak to whether or not it was investigated, but I'm certain it would have been.

Q. And the sentence here from the DEA says, "For example, a system that identifies orders as suspicious only if the total amount of controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient."

That almost perfectly describes

the DEA -- I'm sorry -- the DDM system of populating reports based on averages from month to month, correct?

MR. JOHNSON: Objection.

A. It doesn't describe our total system. It describes the first phase of our system accurately.

Q. It describes the first phase of your system to identify anomalies --

A. Not suspicious orders.

Q. -- on reports?

A. Yes.

Q. Yes. You all didn't consider them suspicious, correct?

A. On those reports, no, not at that point.

Q. So even though an order might have exceeded by 99 percent, you all didn't consider that to be suspicious, correct?

A. Correct.

Q. So suffice it to say, when this letter came out in 2007, DDM never changed its SOM policies to incorporate or identify orders that may be suspicious other than the rigid

formulas, correct?

MR. JOHNSON: Objection.

A. Not to my knowledge.

Q. The second paragraph from the bottom of the page, "Lastly, registrants that routinely report suspicious orders, yet fill these orders without determining that order is not being diverted into other legitimate, medical, scientific, and industrial channels, may be failing to maintain effective controls against diversion."

Do you see that?

A. Yes.

Q. And doesn't that sentence tell DDM that if you're filling orders prior to performing due diligence, you may not be maintaining effective controls against diversion?

MR. JOHNSON: Objection.

A. That paragraph I read as if you are a registrant that routinely has reported suspicious orders but did not do anything about, that would be an issue.

Q. So you all took care of that by

just not reporting any suspicious orders, correct?

MR. JOHNSON: Objection.

A. No.

Q. So you didn't report any suspicious orders --

A. We didn't have any suspicious orders.

Q. Yes, sir. But you didn't figure out whether -- you didn't do any homework to figure out whether they were suspicious or not until the order had already went out the door?

MR. JOHNSON: Objection.

A. The process that is described by the 12-month average and Tom Nameth/Jason Briscoe followed by due diligence would be retrospective, yes. But in a way that would certainly curb or curtail or prevent future issues, if there were any, at a particular location or a particular family of medication at a location.

Q. And that's it exactly. Your system was designed to prevent future problems looking at month-old reports, but there was

nothing in place to cease or halt a shipment that was a potential problem or had been flagged prior to it going out the door, correct?

MR. JOHNSON: Objection.

A. The six-week PO report could certainly lead to that being halted, but that report didn't speak to "this must be halted."

Q. And I appreciate you going routinely back to the six-week report or the fat fingers report, but you can't identify one single instance a suspicious order was not shipped based on that six-week average or the fat finger report, right?

MR. JOHNSON: Objection.

A. Well, I'm not trying to split hairs. If it were identified in that manner, it would not have been a suspicious order. It would have been an ordering error, and it never would have been part of an invoice that would have been intended to be shipped. So we would have cut that off proactively at the pass.

Q. Sure. An ordering error. The fat finger report, you would have cut that off at the pass. Other than someone hitting a 9 rather

than a 6 --

A. I don't --

Q. -- it wouldn't have -- that wouldn't have stopped anything, right?

A. That is one --

MR. JOHNSON: Objection.

A. That's one mechanism by which a quantity that would appear to be much greater than the norm could happen. A fat finger is an example of that happening, or it could be, you know, other -- other examples.

Q. And the only reason we keep going back to this is because you keep referring back to it. But it's crystal clear that if the pharmacist confirmed, "Yes, I ordered that many bottles of hydrocodone," that there is no written policy or procedure in place --

A. That's not true.

Q. -- for DDM --

A. Excuse me. Sorry.

Q. -- to follow up on any criteria on that inventory control report?

A. I wouldn't say --

MR. JOHNSON: Objection.

A. I wouldn't say that's crystal clear.

Q. Well, you certainly can't cite me to anything, right?

A. Well, I can't verbally point you to what the policy or procedure is or if it exists.

Q. Verbally, smoke signals, anything within the months that you've had to prepare yourself for today, you can't tell this jury -- you can't ascribe anything on that six-month average, the fat finger report, that would prevent or identify suspicious orders after confirming with the pharmacist, correct?

MR. JOHNSON: Objection. He's pointed you to a document.

A. Yeah. Today I can't regurgitate if there is a policy and what that policy is.

MR. MOUGEY: If you want to object to the form, Tim, object to the form. But I really don't want to hear your -- your answer from the witness, okay?

MR. JOHNSON: Well, we're going over old ground.

MR. MOUGEY: No. I --

BY MR. MOUGEY:

Q. You've repeated it -- you can't tell me in that document -- the inventory, whatever it is, you can't -- after months of preparation, you can't cite to me or this jury anything in that -- that manual that gives Ms. Strang criteria, thresholds, parameters on that six-week average report, correct?

MR. JOHNSON: Objection.

A. What I can't speak to --

Q. Just yes or no, sir. Can you point me to any written policy --

A. On that report?

Q. -- or procedure on the six-week average -- just give me a simple yes or no.

Can you point me to any policies, any procedures, any criteria on that six-week average report or the fat finger report that Ms. Strang would follow when confirming with the pharmacist?

MR. JOHNSON: Objection.

Q. Yes or no?

A. I can't point you for right now,

but what I don't know and what I don't have memorized is if there are mechanisms outside of this six-week report that could be inclusive of this six-week report as the source by which somebody at the pharmacy warehouse would take action when they see a large quantity come across on a purchase order.

Q. So the answer to my question is "No, I can't point you to any policies, any procedures, anything in writing that Ms. Strang would use on that six-week average report when confirming a purchase order with the pharmacy"?

The answer is --

MR. JOHNSON: Objection.

Q. -- "No, I can't point you to anything."

Right?

A. My answer is I don't have our policies and procedures memorized. If I did and if it were there, I would point you right there. But I don't know if we have them and what they are -- how they are written.

Q. So it's a simple answer. The answer is, "No, I can't point you to anything

specific or generally about policies, procedures, thresholds, ceilings, anything that Ms. Strang could use when calling the pharmacist to confirm a purchase order"? You can't point me to anything --

A. As we sit here --

MR. JOHNSON: Objection.

A. -- right now, the answer is no.

Q. Thank you.

MR. MOUGEY: Good time for a break.

THE VIDEOGRAPHER: Going off the record, the time is 11:58.

- - -

Thereupon, at 11:58 a.m. a lunch recess was taken until 1:01 p.m.

- - -

Thursday Afternoon Session
December 6, 2018
1:01 p.m.

- - -

THE VIDEOGRAPHER: Back on record at 1:01 p.m.

BY MR. MOUGEY:

Q. Mr. Briscoe, I'd like to go back to -- I forget if you were referring to it as Phase 2 or Tier 2, you and Mr. Nameth, DDM performing due diligence on orders that were identified as anomalies shipped, and then you all would perform the due diligence.

Do I have that sequence right?

MR. JOHNSON: Objection.

A. Can you repeat?

Q. Order comes in. It's shipped, placed on an order as an anomaly, and then DDM performs due diligence, correct? Do I have that sequence right?

MR. JOHNSON: Objection.

A. The first phase would be the, you know, review of the report, review of the anomaly, we would characterize due diligence. If that evaluation by Mr. Nameth or myself would

resolve it in a way that we wouldn't need to do the due diligence at store level, then the next level would be due diligence, and that would be communication in that form back to the store.

Q. So you're taking issue with the language "due diligence"? You said that the review of the report, review of the anomaly. You don't call that due diligence? That's fine. I just am trying --

A. No. Formally due diligence would be the third layer, which would be those situations that got -- you know, that Tom or myself identified that deserved communication back to the store, with the store communicating back to us. So that's why I'm making that -- I don't have a problem with your words. I'm just making sure that we're distinguishing the different layers of the SOMS.

Q. Let's take the people out of it, then. Let's say that order comes in, okay? It's shipped.

Are we still on the same page?

A. Assuming that there wasn't anything along the way that would have prevented

it from being shipped, such as the six-week average report, yes.

Q. So let's do it that way. So order comes in. It passes the scrutiny of the fat fingers report, right?

A. The six-week average report.

Q. Then it's shipped, okay? So -- and then it's shipped after the six-week average or fat fingers report, right?

A. Yes. Yes, sir.

Q. All right. So after that, if it meets one of the thresholds we discussed previously and is identified as an anomaly, it goes on the SOMS report, correct?

A. Yes.

Q. And the first review of that is you or Mr. Nameth reviewing that anomaly report, right?

A. Yes.

MR. JOHNSON: Objection.

MR. MOUGEY: What's the basis for the objection?

MR. JOHNSON: You're saying the first review of it. I mean, as I

understand his testimony, there's a number of different components to the whole SOMS thing. The six-week report, Jill's intervention, then the --

MR. MOUGEY: Okay. So your basis is that I'm mischaracterizing the evidence? I didn't want a recitation. Just did I miss --

MR. JOHNSON: Oh, I'm sorry. Yes. We skipped the Jill part.

BY MR. MOUGEY:

Q. Did Jill at any point in time, Ms. Strang, ever bring to you an order that she wanted you or Mr. Nameth to review as a potential issue for diversion?

A. I don't recall her bringing one to me.

Q. Okay. Did you see any evidence in your preparation today that Ms. Strang had ever brought an order to you -- I'm sorry -- to Mr. Nameth with his help as -- to review for potential diversion?

A. No.

Q. So the order comes in. It doesn't

trigger the six-week average or the fat finger order, okay? And -- but it does trigger the 52-week average threshold, okay?

Do I have the sequence right?

A. Yes.

Q. All right. The order is still shipped, correct?

A. Yes.

Q. Now, you and/or Mr. Nameth receive the anomaly report once a month?

A. Yes.

Q. And that is what you were referring to as the -- was it Phase 2 or Tier 2?

A. Generally speaking or, you know, in common terms, yes, Phase 2.

Q. Okay. Phase 2.

I'd like to have you explain to the jury in the Phase 2, after the order has already gone out the door, what is DDM's policy in writing about what should be done with those orders on the anomaly report?

A. As I mentioned earlier, I believe the written policy speaks to review by pharmacy operations.

Q. Okay. So just you and/or Mr. Nameth taking a look at the report?
A. Yes.
Q. All right. So --
A. And, you know, taking further steps once we've taken a look at the report.
Q. So once you've taken a look at the report, what are you -- what are you looking for?
A. First off, is it a medication that might be new to our distribution facility.
Q. Okay.
A. So if this was something we were obtaining -- a family that we were obtaining from another supplier, such as a wholesaler, and now we are purchasing it from our own distribution center, that would be an example of something presenting as an anomaly that can be legitimately explained, because we're no longer procuring that medication from the wholesaler and now procuring it from our distribution center.
Q. All right. What --
A. Another --

Q. Go ahead. No, go ahead. I'm sorry.

A. Another example would be an ordering pattern which can be explained by the dispensing pattern of a medication at a store.

Q. Can you explain that a little more when you --

A. Sure. So if we're looking retrospectively over the last 12 months -- and I'll use the same example as earlier -- is that if the ordering pattern of that store for that family had been two bottles, zero bottles, two bottles, zero bottles and plays out over 12 months, the subsequent month, if we were to place -- and let me pause there. That would equate to a 12-month average of one bottle.

And let's take it a step further on what I would do. Let's say that bottle was the 500-count the entire step of the way. So, therefore, there was an average of 500 units shipped to that store per month for the last 12 months. If that pattern continues six out of those 12 months, it would pop as an anomaly because two bottles or 1 000 units is greater

than 99 percent than one bottle or 500 tablets.

And if I were then to go at that store specific to that family to look for a legitimate dispensing history, I would see that the pattern of how we're dispensing dictated the pattern by which they're ordering and were shipping. Therefore, that would not go on to the next level of due diligence, asking the store, "Please explain why you ordered two bottles instead of one."

Q. Let me see if I can simplify what your explanation is. Maybe my head is just a little smaller than yours.

You have 12 months, okay? Six months you order, your example, 1,000. The order comes in for 1,000. Six months it comes in for zero. That averages 500.

A. Yes, sir.

Q. Is my math right?

A. Yep.

Q. Okay. Thirteenth month, an order comes in for 1,000. That's more than 99 percent and would be --

A. An anomaly is what we've

characterized it.

Q. So you'd look at that and think, "Well, every other month they're ordering 1,000" --

A. I wouldn't think. I would go -- go into the store's dispensing history to see what reality is and then determine if it requires the next level of due diligence involving the store's feedback.

Didn't mean to interrupt you.

Q. No, that's okay.

So same example. Month 13, the next year -- second year, let's just call it -- the average is now 1,000, okay? 1,000, 1,000, 1,000, 1,000, every month. So your order in year 1 was 500. Your order in year 2 was 1,000. Those are averages.

A. Over the 12-month period?

Q. That's right.

A. Okay.

Q. Okay? So your average has now doubled. So just take this to its logical conclusion. Thirteenth month, you see, yeah, one month zero, one month 1,000. You contact

the pharmacy -- pharmacist. You look at their legitimate -- what you've described as legitimate dispensing and you think, "Yes, it's 500, but one month it's 1,000, one month zero. That's why it's on the report."

Am I capturing that right?

A. Yes. I don't think we could get to your example on that 13th month without having other situations along the way that would have led to an anomaly populating. So if we're going from an average of 500 in this 12-month period to an average of 1,000 in the next 12-month period, there would have been some anomalies that would have headed towards that 1,000.

Q. Because you would have seen it along the way --

A. Yes.

Q. -- and that would have triggered the 99 percent.

So now, second year, same fact pattern to keep it simple, okay? Now 1,000 a month. It's double what it was in year 1. Okay? The first month of year 3 comes in, and

it's 2,000. Do you look back at the dispensing history and, although the average was 1,000, one month was two, one month was zero, one month was two, one month was zero, same fact pattern as year 1, excepting for now it's two and zero and the average is one, rather than one and zero and the average is 500. It's now doubled.

A. Yep.

Q. Okay? What do you do then?

A. So not every -- not every example am I looking solely on ordering patterns or dispensing patterns. There would be other areas that we would be looking into.

Q. Like what?

A. Potentially a pharmacy down the street closed, a new prescriber's office in the area. You know, local knowledge in that we're intimately connected to all of our stores, we have an understanding on -- on what could lead to -- lead to the legitimate increase of dispensing medications under legitimate medical purposes.

Q. Okay. Is there any others? I've got new prescriber, pharmacy down the street,

family from another supplier, ordering pattern explained by dispensing pattern.

A. New patients.

Q. New patients?

A. Yep. So let's say it's a relatively -- well, it could be any store and, you know, we're increasing our business not specific to opioids or controlled substances. But generally speaking, more people are coming into our doors to take advantage of the care we provide as pharmacists. So a natural progression in prescriptions dispensed of any type would also explain a natural progression in what had been shipped to the store.

Q. All right. So we have just added new patients. Anything else?

A. I mean, transferred prescriptions would -- would constitute new patients. If there were a recall of a medication --

Q. Mm-hmm.

A. -- and now all of a sudden everything that was on the shelf had to be sent for destruction and we have to replenish the level that we were at, but did so in a way that

was one purchase order versus several purchase orders for several months to get back to that level, that would be an indication of a legitimate reason why that store ordered a family greater than the 12-month average.

Q. All right. So Phase 2, looking for or identifying issues that would explain the anomaly. Am I saying that correct?

A. Yeah.

Q. Okay. Anything from new prescribers to new patients, a pharmacy closed down the street, just transferred over from another supplier. Anything else you can think of that you're looking for on the -- to answer questions on the anomaly?

A. If there was a known loss or theft and that medication is no longer in stock and we have to replenish it, that would be another example of --

Q. Okay.

A. -- replenishing it beyond what would be typical.

Q. Anything else you can think of?

A. New product comes to market and

there isn't a past order history.

Q. Mm-hmm.

A. I might have mentioned that already.

Q. Anything else you could think of sitting here today?

A. Not at this time.

Q. All right. All of those that you just walked me through were looking for reasons to explain the reason for the anomaly, correct?

A. Can you restate that.

Q. Everything you just -- every one of those bullets you've just walked me through in the last ten minutes are looking for reasons to explain the anomaly?

A. It could give us comfort in knowing that that medication deserved to be shipped.

Q. Exactly. And, retrospectively, looking to approve or explain away the order that popped on the anomaly so it wouldn't be suspicious, right?

A. So it wouldn't then head to due diligence with that form we've discussed

earlier.

Q. Yes, sir.

So when do you contact the pharmacy? At what point in time? When in this process of Phase 2 do you contact the pharmacy?

A. In Phase 2? Okay.

Q. Whatever phase you got --

A. Yep.

Q. -- just tell me when you contact the pharmacy as we --

A. If there were information I could not glean from the dispensing system with me having access --

Q. Mm-hmm.

A. -- to the prescription history and the scenarios I've just described, if there were other factors that I wasn't readily aware of, such as a pharmacy down the street had closed or a new prescriber's office just moved into the area --

Q. Mm-hmm.

A. -- that type of local knowledge, if I didn't have that and still wasn't satisfied based on what I was looking at from ordering

patterns, et cetera, I would -- I would then call the pharmacy.

But if your question is related to when do I send the pharmacy what we call a due diligence report --

Q. Right.

A. -- like, it's if everything that we just walked through, I still want more information that I can't find or don't have --

Q. Mm-hmm.

A. -- that's whenever we send a form to them to say, "Here's what happened. We need information from you as to why that happened."

Q. Right. You send that form to the pharmacy, and you call that the due diligence report?

A. Yes.

Q. And you ask the chief pharmacist to fill it out?

A. Yes.

Q. And that's when you can't explain the anomaly based on the factors you just gave me, right?

A. Yes, sir.

Q. Okay. And the chief pharmacist or the staff pharmacist fills that out?

A. Chief pharmacist, I believe, is -- if they're available, is who was on the form, I believe.

Q. Is there -- I'm sorry.

A. Go ahead.

Q. Is there a time limit on when they can get that back to you?

A. I believe the verbiage is ASAP.

Q. Okay. And do you have a -- and what's that mean? That means different things to different people.

A. That means if we don't hear back from them, you know, that day or the next day, we'll be following up with a phone call.

Q. A couple days.

And there's a form -- is that form stored anywhere at DDM?

A. Yes.

Q. Where is it stored?

A. It's stored electronically in a folder -- I think C -- controlled inventory -- I can't remember the name of the folder, but it's

electronically stored that we have access to in a --

Q. So you mentioned early in the deposition that you had worked at gathering answers and responses for this litigation, right?

A. Yes.

Q. And I'm assuming you went to where these were stored and directed your counsel that here's where they are and all of them were produced, right?

A. Yes.

Q. And those were kept in the ordinary course of business and digitally, so if you wanted to look back at them, you could?

A. Yes.

Q. And how were they organized?

A. By store, by date, labeled with item included.

Q. Okay. So in the course of this litigation, is it safe for me to conclude that I have those due diligence reports from the pharmacies as you or Mr. Nameth sent them to the pharmacies and received them back. They would

have been produced to us?

A. Yeah. From 2006 to 2014 in --

Q. Yes.

A. -- Summit and Cuyahoga County related to opioid products.

Q. Do you have just a recollection sitting here generally of how many reports there were?

A. I believe there were 11.

Q. Okay. So do you have a general understanding of how many dosage units DDM has put into commerce in the State of Ohio from, you know, the last ten years or so?

A. You mentioned a number earlier.

Q. I mentioned 72 million.

A. Mm-hmm.

Q. And I've pulled that number from ARCOS, hydrocodone. And you understand what ARCOS is, right?

A. Yeah. And that would be all stores?

Q. That would be all the stores within the Ohio network of DDM.

A. Okay.

Q. All right. So about 11 times, DDM couldn't answer the question of the anomaly on the report and they went to the pharmacist?

A. Yes.

Q. All right. And I'm going to hand you what I'm going to mark as Briscoe 9.

- - -

(DDM-Briscoe Exhibit 9 marked.)

- - -

Q. So Briscoe 9, at the top of the page, Confidential. Attention: Chief Pharmacist.

Is this an example of one of the due diligence reports you were referencing?

A. It is.

Q. So the first paragraph says, "The Drug Enforcement Agency, U.S. Department of Justice, has requested that Discount Drug Mart pharmacy operations maintain records of controlled substances purchases that exceed an average of purchases calculated from the previous 12 months or that deviate substantially from normal average per month."

Correct? Did I read that right?

MR. JOHNSON: Correct, you read it right?

MR. MOUGEY: Yeah.

A. Yes.

Q. Now, is that an accurate statement that the DEA has requested that DDM use a formula from the previous 12 months?

A. I can't speak to whether that request came from the DEA to somebody else. My gut says that was meant to provide some urgency to those that would be receiving it and that our intent was to make sure that they understand the importance of what we're sending them.

Q. So quite frankly, the formula, based on the previous 12 months, runs counter to the direction from the DEA that we just reviewed in the 2006 and 2007 correspondence, right?

MR. JOHNSON: Objection.

A. Well, I would argue that the fact that we're looking at a rolling 12 months gives us a more accurate and actionable view if there is, indeed, an anomaly based on the last 12 months, rather than looking in the document that you had provided month versus month versus

month. I think there's probably more false positives or more false negatives associated with only looking at from one month to the next. I don't think you're going to be as accurate as what we're -- we were doing with a 12-month rolling view.

Q. Now, the document that you're referencing that I handed you isn't a Peter Mougey document. That's from the DEA, right?

A. Yeah.

Q. And the DEA has relayed to its registrants that it not use a formula, correct? So when you say -- you said, "I would argue," you're not arguing with me; you're arguing that the DEA don't use a formula was wrong? Right?

MR. JOHNSON: Objection.

A. No. I think we've explained that -- and I can't recall the paragraph that we spoke about earlier, but we certainly don't lean on the report alone to trigger due diligence. That's why there's Phase 2 with Mr. Nameth and myself being involved.

Q. Why don't you grab back in front of you Briscoe 8.

A. Sure. I have it.

Q. The second page of Briscoe 8 says, "Registrants that rely on rigid formulas to define whether an order is suspicious may be failing to detect suspicious orders."

So let's just start here. Let's compare Briscoe 8 and Briscoe 9. Briscoe 9 relays that the DEA has asked us to maintain records of controlled substance purchases that exceed an averages of purchases calculated from the previous 12 months, right?

Is that a formula, previous 12 months, that you're using?

A. Yes.

Q. Is it a rigid formula?

A. I think we agreed --

MR. JOHNSON: Objection.

A. -- we agreed that it was, but it was also not the only phase of our SOMS.

Q. All right. But all I'm asking you right now is about the formula that populates --

A. I understand.

Q. -- the anomalies, right? I understand.

Okay. So where I'm a little confused is you said, "Well, where I would argue with you is that our formula provides more than a month to month to month."

There's nowhere in any guidance from the DEA that you can point me to that the DEA has asked DDM to run an average of purchases calculated from the previous 12 months, correct?

MR. JOHNSON: I'm going to object, but --

A. Again, to my knowledge, yeah.

Q. All right. In fact, the DEA has told DDM that a system that identifies orders is suspicious only if the total amount of controlled substance ordered one month exceeds the amount ordered the previous month by a certain percentage is insufficient.

Do you see that?

A. Is that 8 or 7?

MR. JOHNSON: That's 8, second page, first paragraph.

Q. Same paragraph we were just on. 8, second page, second paragraph.

DEA says that the total amount of

a controlled substance ordered during one month exceeds the amount ordered the previous month by a certain percentage or more is insufficient, correct?

A. Yep. Yep. And I think whenever we were speaking of this earlier, I agreed with you that that sounds an awful like -- a lot like our system. And, in actuality, the first phase of our system, which triggers the anomalies to populate on a report, is not this exactly, because this speaks to looking only one month back, whereas we look a rolling 12 months back.

Q. Now, did that come to you over lunch, when you were having lunch with your counsel and the corporate representative?

A. I was just replaying conversations in my head.

Q. Mm-hmm.

So the system that DDM had, you feel, is using the rigid formula of an average of 12 months and that 13-month or whatever time during that period would exceed by 99 percent, you believe that that was a system designed to report suspicious orders, correct?

MR. JOHNSON: Objection.

A. That was Phase 1 of our SOMS, yes, sir.

Q. So now we have Phase 2, and you're trying to explain the reason for the anomaly and you can't. So in 11 instances from 2006 to 2018, the chief pharmacist was sent a due diligence report, correct?

A. Yes.

Q. All right. And the chief pharmacist is asked to fill out the reason why there on the bottom, correct?

A. Yes.

Q. And DDM fills out the top portion, and in this example, Briscoe 9, an April 2008 report indicates an increase in purchases is hydro -- is that Bit?

A. It's Hydrocodone Bitartrate/Acetaminophen 10/325 would be what --

Q. Yes.

A. -- that abbreviation stands for.

Q. And the next series of numbers is the NDC code?

A. Yes, sir.

Q. Your average monthly purchases of this item are 3.0 bottles. This month 11 bottles were ordered, correct?

A. Yes.

Q. And it goes on and says, "Please verify this quantity and provide appropriate explanation as to the necessity of the increase. Thank you for immediate response to this request. Please complete requested information below and return to pharmacy operations ASAP."

Do you see that?

A. I do.

Q. And the explanation for the order increase was had two or three prescriptions for larger amounts than usual -- I can't read that next word.

A. Directions -- or excuse me. "Quantities were verified with physicians."

Q. All right. So I'm assuming, since DDM never found an order suspicious, never reported anything to the DEA, that that explanation was sufficient.

A. Yes.

Q. So when quantities were verified

with physicians, as long as the pharmacist said, "Called and spoke with the physicians," then everything was okay?

A. Yeah. So if the prescriptions were filled without the double-check of following up with a physician to confirm the quantity, that potentially could have led to a resolution to this. But, again, this was one Tom had worked on. The fact that the pharmacist took the time to double-check that this prescription for a larger-than-usual quantity had been prescribed, that pharmacist felt it necessary to call. And when they spoke to the physician, he was satisfied that, "Yes, I'm going to go forward in dispensing this medication."

Q. Now, I have not seen any reports from DDM the entire time where -- well, strike that. I'm going to do something different.

We talked about doctor shopping earlier, right? And one of the problems with pills making their way into the illicit or illegal drug trade was through doctor shopping, right? You agree with me?

MR. JOHNSON: May I interrupt?

Well, I'll object, but is that a defined term someplace, just for my information?

MR. MOUGEY: Which part?

MR. JOHNSON: Doctor shopping, or is that just vernacular?

BY MR. MOUGEY:

Q. Do you know what I mean by "doctor shopping"? I asked you earlier. I think you gave us an explanation, right?

MR. JOHNSON: He gave you his definition.

Q. You're familiar when I say "doctor shopping" that -- you gave me an explanation before, correct?

A. Yes.

Q. All right. So you understand that doctor shopping was one of the ways that pills made their way into the black market or illegal drug trade, right?

A. Yes.

Q. And DDM, through its databases, could identify the highest -- the physicians

with the highest percentage of Schedule II and Schedule III prescriptions, correct?

MR. JOHNSON: Objection.

A. Could we?

Q. Yes.

A. We could.

Q. Pretty easy, right?

A. I wouldn't say it's easy.

Q. You just run a query in the database and run it by -- sort it by prescriber and then sort by Schedule II and Schedule III, right?

A. A little more complicated than that based on the way our pharmacy management system works, but I understand what you're saying.

Q. All right. But this is a company that's -- DDM does about 400 million in sales per year, right?

A. I don't believe that's accurate.

MR. JOHNSON: Objection.

Q. You had 400 million in revenue?

A. Are you speaking specific to the pharmacy?

Q. I'm talking to the whole operation.

A. I think that number is greater than that.

Q. Do you have an understanding that -- that DDM hired a lobbyist or an individual to help meet with regulators in D.C.?

MR. JOHNSON: Objection.

A. No.

Q. Do you have any understanding that DDM has ever hired anyone to handle its affairs with any governmental issues out of D.C.?

A. A lobbyist?

Q. And I rephrased it and took out the word "lobbyist." I said hired anyone to deal with any governmental body -- bodies in D.C.

MR. JOHNSON: Objection.

A. We have a gentleman on staff that his title is related to legal and regulatory affairs.

Q. Yes, sir. And he interacts regularly with governmental entities, correct?

A. Regularly, I'm not -- not sure.

Q. He reports back to DDM on what his -- what his -- the results of his -- fruits of his labor, the results of his meetings? Are you familiar --

A. Sure.

Q. Okay. And that's part of his job description, right?

A. Yes. To my knowledge, yes.

Q. So DDM could query their databases, has the capability to do that, to identify higher risk prescribers, correct?

A. Would we have the ability? Yes.

Q. Yes. I have not seen one report generated by DDM identifying physicians that have high percentages of their prescriptions coming from Schedule II and Schedule III opiates. Can you point me anywhere that DDM was running reports similar?

A. Specific to the distribution center?

Q. Specific to physicians that were writing disproportionately high percentages of Schedule II and Schedule III prescriptions.

MR. JOHNSON: Objection.

A. I would say that reports definitely have been run. I wouldn't say that they would be done on a systematic basis from the corporate level or from the distribution center. But associated with our controlled substance quality assurance program, whenever there's a resolution of red flags when it comes time to dispense medication, you know, that would be part of the red flag identification work to resolve it and -- and documentation.

So they would be looking at -- if they were suspicious of a particular prescriber, they would have access at store level to run those types of --

Q. Mr. Briscoe, we're sitting here talking about suspicious order monitoring policies, are we not?

A. Yeah.

Q. We're talking about DDM's responsibility under CFR 1301.74; are we not?

A. We are.

Q. We're talking about all of the different policies and procedures in place, correct, sir? There's not any question about

what we're talking about, correct?

MR. JOHNSON: Objection.

A. Yeah.

Q. Is there any -- is there any policy or procedure that DDM was running to identify high risk prescribers in response to any of the orders that were identified as anomalies?

MR. JOHNSON: Objection.

A. There are not reports we've run on a regular basis as part of the Phase 1 that -- if -- if that's what we're referring to, identification of anomalies.

Q. But what I asked you, sir, was, is there any policy -- I need you to answer so we can, despite the snow, get out of here. Okay?

Is there any policy or procedure that DDM was running to identify high risk prescribers in response to any of the orders that were identified as anomalies?

MR. JOHNSON: Objection.

A. It's not part of the Phase 1 of our SOMS, but I -- reports can and have been run based on specific circumstances that would have

us taking a deeper look.

Q. We've gotten through the "can they be run." I understand. You told me, "We can run it through a query." I get that.

A. Okay.

Q. Okay? But what I asked was, is there any policy or procedure that necessitates that DDM use a report to identify high risk prescribers through a high percentage of Schedule II and Schedule III in response to any of the anomalies?

MR. JOHNSON: Objection.

A. Can I ask you a question to clarify? Is that ahead of a prescription being presented at a store where one of our pharmacists would be evaluating the legitimacy of that prescription, of which would be making sure the prescriber not only is prescribing something legitimate, but they're legitimate themselves?

Q. I'm talking about DDM's responsibilities as a distributor.

A. Part of our responsibility as a distributor is to know our customers. And I

could tell you the totality of our efforts in knowing our customers --

Q. I don't want to hear the totality of your efforts. I'm asking a very, very specific question. I've asked it three times.

A. I'm not trying to dance around it.

Q. Can you point to --

MR. JOHNSON: He's answered it three times, too.

MR. MOUGEY: I'm sorry, but I don't feel like it, and I don't feel like I'm getting a straight answer.

BY MR. MOUGEY:

Q. Is there any policies or procedures that require a look or review of the high risk prescribers dispensing a disproportionate high percentage of Schedule II or III in response to an order being placed on one of the reports as an anomaly?

MR. JOHNSON: Objection.

A. The very specific way you've phrased that, the answer is no.

Q. Can you point me to any -- any report, anything that you've run and DDM has

kept, where it's analyzing high risk prescribers through a disproportionately high percentage of prescriptions of Schedule II and Schedule III opiates?

MR. JOHNSON: Objection.

A. Specific to the distribution center, no. Resolution of red flags on a prescription-by-prescription basis, I think we would -- we would find.

Q. We've already gone over that. We've already discussed DDM's responsibilities as a pharmacy and DDM's responsibility as a distributor. All right? So now I understand that -- that maybe you want to point me to DDM as a pharmacy, but I'm asking you as a -- DDM as a distributor.

Do you understand we're here --

A. I'm with you.

Q. Okay.

MR. JOHNSON: These questions are strictly about distributors.

Q. You understand that we're here today talking about DDM as a distributor and the access to information it has, right?

A. Yes.

Q. And it has access to information also in its role as a dispenser, correct?

A. Yes.

Q. But in its role as a distributor, can you point me to any reports that it's running to identify high risk prescribers through a disproportionate prescriptions of Schedule II and Schedule III opioids?

MR. JOHNSON: Objection.

A. No.

- - -

(DDM-Briscoe Exhibit 10 marked.)

- - -

Q. I'm going to hand you what I've marked as Exhibit 10. I'm going to hand you a series of these.

Is this another example of the due diligence report?

A. It is.

Q. And the average monthly purchase of this item went from 2.8 to 8.6, right?

A. I believe, looking at this, there -- this report contains two medications,

and their respective increase would be from 0.9 to 8 and 2.8 to 6.

Q. I want you to turn to that -- I can't read the bottom. Can you?

A. I can't.

Q. Okay. Second page, which appears to be a computer printout. Explain to me what this is.

A. So for the respective NDCs that were identified on the top half of the report, this is the dispensing history by that NDC from April 1, 2012 through May 25, 2012.

Q. So --

A. Go ahead.

Q. -- just looking for a reason to explain the reason why it popped as an anomaly?

A. Looking for -- step one would be making sure that there were prescriptions that were dispensed totaling the quantities that we have shipped, meaning if there were fewer tablets on their shelf plus what's been dispensed, and that's less than what had been shipped, that's an opportunity or an example of potential diversion, meaning where did those

tablets go.

So first step it appears Tom took was to ensure that the math made sense on the total dispensing compared to what that store had on hand before the shipment and what they would have had on hand after that larger-than-average shipment.

Q. And, again, the question I simply asked was, looking for a reason to explain why it popped as an anomaly, correct?

A. Yes.

Q. Yes.

- - -

(DDM-Briscoe Exhibit 11 marked.)

- - -

Q. Exhibit 11, Briscoe 11, another example of a due diligence report dated 9/18/2012, correct?

A. Yes.

Q. And, again, second page, a copy of the dispensing history, looking for a reason to explain the reason why the anomaly popped, correct?

A. Yes.

- - -

(DDM-Briscoe Exhibit 12 marked.)

- - -

Q. Briscoe 12, another example of a due diligence report with an example of hydro, October 13, three bottles to 16 bottles, correct?

A. Yes.

Q. A 530 percent increase, correct? Five times --

A. I'm trusting your math.

Q. Five times, right? Five times -- 5 times 3 is 15, right?

A. Plus one.

Q. Plus one. One is one-third of three, approximately 530. 533 percent increase in one month?

A. Without getting a calculator out, yes, I will --

Q. Turning to page 2, a printout of the dispensing history, correct?

A. Yes.

Q. And, again, looking for a reason to explain why it popped as an anomaly, correct?

A. Yes.

- - -

(DDM-Briscoe Exhibit 13 marked.)

- - -

Q. Briscoe 13, another example of a due diligence report dated 11/11/13, correct?

A. Yes.

Q. Zero bottles to 22, correct?

A. Yes.

Q. And the explanation is below the dispensing history, correct?

A. Yes.

Q. And the chief pharmacist referenced the -- the dispensing history and amount of inventory on our shelf, correct?

A. Yes.

Q. And, again, that order wasn't identified as suspicious either, correct?

A. I think he also pointed to -- there was a -- a situation with the auto reordering system over-ordering and that they accounted for all of the quantity that had been ordered.

Q. Why wouldn't the six-month average

have picked that up, the fat finger report that came in when the inventory was already there?

MR. MOUGEY: Objection.

A. I don't know.

- - -

(DDM-Briscoe Exhibit 14 marked.)

- - -

Q. Briscoe 14, one of the 11 due diligence reports over a period of 12 years, another hydro issue, correct?

A. Yes, sir.

Q. Two bottles was the average and ten bottles that month, correct?

A. Yes.

Q. Now, how can you tell how many dosage units two bottles to ten bottles went to from looking at this?

A. The NDC, which isn't on this example, would -- would get you there.

Q. The NDC code in the middle of the page is -- is blank, correct?

A. It's down below on the bottom half, but, yes, it was blank on the top.

Q. So this is 2008. This is during

your tenure, correct?

A. No.

Q. Who's tenure was this?

A. Tom Nameth.

Q. Oh, I'm sorry. Yes. Mr. Nameth's time period.

The NDC code is blank. So for the top half of this when he sent it out, it's impossible to discern how many dosage units we're talking about, correct?

MR. JOHNSON: Objection.

A. No. It could have been a -- I'm not excusing it, but it's simply a clerical error where he left that field blank, but he well could have known or should have known or did know how many units we were talking about.

Q. Now, this report is not organized by NDC code, right?

A. "This"?

Q. I'm sorry. The 52-week average report is not organized by NDC code, correct?

A. It's not grouped by NDC --

Q. Okay.

A. -- it's grouped by family.

But every NDC that would have been shipped in that month would have been exposed.

Q. So I'm having trouble connecting the dots on that. If it's by family, which would mean hydrocodone based on different strengths essentially?

A. No -- no, sir. When I speak of family, what I mean is in this example, hydrocodone with acetaminophen 7.5 milligrams/500 milligrams.

Q. Okay.

A. There isn't just one manufacturer of that product available in the marketplace.

Q. Okay.

A. So if there are multiple manufacturers of that same generic family, which means same drug, same strength, same dosage form, we have interest in and need to have visibility to all activity, not just based on an NDC, but that entire family, because that's relevant information in knowing that you might be getting this NDC which is equivalent to the other NDC, and if we don't have visibility to both on that report, that creates opportunities

for, you know, missing the anomalies.

Q. So this is an example of a report where the average over the 52 weeks goes up by 500 percent, and this explanation from the pharmacist met with your or DDM's approval, correct?

A. Yes.

Q. So, as a matter of fact not -- you can't point me to one time ever at DDM from 2006 to now that one of these due diligence reports from the chief pharmacist were ever denied or deemed suspicious?

A. Correct.

Q. So is it safe to assume that there is no policy or procedure after receiving back these due diligence reports about what further inquiry was necessary?

MR. JOHNSON: Objection.

A. No, but we would trigger an investigation with pharmacy operations and loss prevention, and if, upon that investigation we found there to be issues, we would then communicate with the local State Board of Pharmacy, the DEA. If law enforcement was

necessary, we would speak to them as well.

Q. Can you point me to any time or any order that triggered an investigation with pharmacy operations and loss prevention where you communicated with the local State Board of Pharmacy, the DEA and/or law enforcement?

A. No, sir.

Q. Never? Not once?

A. No.

Q. Is that policy or procedure that you just mentioned, wherein the due diligence report would return from the chief pharmacist and there was still a problem, is there anywhere that that policy or procedure is written down?

A. As a continuation of the SOMS, I don't believe so. But anytime that the potential for diversion is detected, yes, we have a written procedure that would speak to an open investigation at that point to open an investigation.

Q. All right. So where is that written procedure that would speak to an open investigation? Where is that?

A. To opening an investigation?

Q. Mm-hmm.

A. From a -- at store level, it would be part of our CSQA. At the warehouse, it would be in our warehouse manual policies and procedures.

Q. Are you talking about like DEA Form 106s?

A. That would be if -- if an investigation following --

Q. A theft?

A. -- a situation led to a known loss or -- a theft or known loss, then, yes, we would head down the path of contacting the State Board of Pharmacy, law enforcement, if necessary. We would notify the DEA with the facts and then be sure to follow up with a 106.

Q. Sure. And that all sounds great, and I appreciate that explanation about the 106 form, DEA Form 106s that covers thefts, right? Correct?

A. Yeah.

Q. All right. So what I'm driving at is, in -- in DDM's responsibility as a distributor with a system designed to identify

and report suspicious orders, after you receive that, quote/unquote, due diligence report back, is there anything in writing giving pharmacy operations guidance on what further inquiries should be made?

MR. JOHNSON: Objection.

A. Can you repeat the first part.

Q. Sure.

A. Lead me into it again.

Q. DDM's responsibility as a distributor with a system designed to identify and report suspicious orders, once you get that, quote/unquote, due diligence report back, is there anything in writing giving pharmacy operations guidance on what further inquiries should be made?

A. Well, again, not specific to the extension of the SOMS leading to the due diligence, but if there's any evidence of diversion, we would trigger what I described. And I believe those policies are found in the two places that I had mentioned, if not additional places.

Q. But sitting here today, you can't

point me to anything specific about criteria, thresholds, parameters, ceilings, anything relating to that due diligence report as it's coming back?

A. Well, I --

MR. JOHNSON: Objection.

A. -- I thought we were speaking of diversion, and I don't know that we would treat the reporting of diversion any differently based on the level of diversion we thought it to be. If we identified it as potentially diversion, it would -- it would be reported.

Q. I don't think I asked you anything about the magnitude of it. Let me do it again, okay?

Can you point me to anything specific -- criteria, thresholds, parameters, ceilings, anything -- that gives DDM and its pharmacy operations direction as to what to do when that due diligence report comes back?

MR. JOHNSON: Objection.

A. It all depends on what we learn when the due diligence report comes back if -- if we continue to go forward. And

unfortunately, we don't have -- or fortunately, we don't have examples to point to.

But if we learned that an order was, indeed, suspicious and what made it suspicious is we believed that there was some type of diversion that took place, we would trigger the steps I just described.

Q. But as of right now, you've defined absolutely nothing to me criteria-wise, looking at any of these anomalies, going to the chief pharmacist, other than criteria trying to explain the reason for the anomaly?

MR. JOHNSON: Objection.

A. I guess the point I'm trying to make -- and maybe I'm not doing a good job -- is if we determined that one pill was stolen by a pharmacy technician, that wouldn't necessarily be tied to a threshold, et cetera, meaning if we identified that to be diversion because we -- we deemed it to be or learned that it was as part of the investigation, then we would -- we would report.

Q. Okay. Is the 52-week average rolling or based on what period of time? What

52 weeks?

A. Rolling.

Q. Rolling. So do you see any issues with using averages?

A. Certainly.

Q. Do you see any problems using averages in a formula when spotting potential suspicious orders?

A. Yes, and -- but --

Q. What happens with averages over long periods of time?

A. What I'm saying is --

MR. JOHNSON: He had more to say, I think.

A. And I think they used -- they used the word "rigid." And, again, that -- that's why that report doesn't stand alone. That's why that report only produces anomalies to be reviewed by Tom, because we recognize that that report is not enough. But that doesn't make our SOMS, in our view, any less effective. It's just part of the process.

Q. That wasn't what I asked. Could you just focus on what I asked you, okay?

What I asked you was, do you see any issues or problems -- and if the answer to my question is yes, I do see issues or problems with using 52-week averages, then please just say yes, okay, because what you just answered me was, "Well, I had a whole -- this broad system with Mr. Nameth."

So I get that you want to focus on Mr. Nameth, but what I'm asking you is, is the formula -- using a 52-week average, do you see potential problems with that as a system designed to spot suspicious orders?

MR. JOHNSON: Objection.

A. If that system is in a vacuum standing on its own with no other phases to it, yes.

Q. So that system in and of itself is what's designed to spot anomalies warranting further review, correct?

A. That is a report, not a system, yes, that identifies --

Q. That is a system in its entirety, Mr. Briscoe, to identify orders that were anomalies warranting DDM's further review,

correct?

MR. JOHNSON: Objection. And, really, Peter, you don't need to raise your voice, sir. You're here to ask questions respectably, and he's answering your questions respectably, I believe, so ...

Q. Please just answer my question. Okay? I'm not -- my -- I'm sorry, but I don't believe you are answering my questions. You're answering questions which you -- which you're attempting to see where I'm going three -- three issues down the cycle.

I'm simply asking, the entire system designed to identify suspicious orders -- just let me finish.

A. Sure.

Q. The entire system designed to identify anomalies warranting DDM's review was the formula, correct, sir?

A. In addition --

MR. JOHNSON: Objection.

A. In addition to the six-week average. But, yes, the last way that you

described it, anomalies was right. The last --

Q. Which are both formulas, are they not, sir? Six-week, 52-week, they're both averages, right?

A. Yeah.

Q. Look, you have your Ph.D., right? I mean, you're -- you have a doctorate degree, correct?

MR. JOHNSON: Wait. Wait. No. Hold on.

Q. You have a doctorate degree, correct, sir?

MR. JOHNSON: Let's not get down to that level.

Q. But you know what "averages" means, correct?

THE COURT REPORTER: Wait a second. One at a time.

Q. You know what an average means, right?

A. Where I was not answering your question, sir, was when you spoke to that being our system to identify suspicious orders, and all I wanted to make sure you were saying was

that is the system to identify anomalies. And you did it the last time, and that's why I answered yes.

Q. No, you didn't answer yes. You answered yes and then you wanted to talk about the six weeks. So let's do it your way.

The six-week average report and the 52-week reports were the entirety of the system designed to identify anomalies for further DDM review, correct?

A. Yes, sir.

Q. And the entirety of DDM's system to identify anomalies was based on averages, correct, sir?

A. Yes.

Q. And, sir, you understand that there are problems associated with using averages to identify anomalies, do you not, sir?

MR. JOHNSON: Objection.

A. I would identify that if problems is one way to characterize it or there's more work that needs to be done in the review process because that report only focuses on averages.

Q. You would agree with me, sir, that

using averages as a system designed to identify anomalies warranting further review from DDM was not precise enough?

MR. JOHNSON: Objection.

A. I would answer that it could be more precise.

Q. Thank you.

And part of the reason why those formulas in both the six-week average and the 52-week average were not precise enough was the use of averages with no further identifying factors, correct, sir?

MR. JOHNSON: Objection.

A. Could you please reask that.

Q. Sir, when you use averages -- let's go back to the example we were going through before.

Averages over 12 months, the average 500, zero, 500, zero -- I'm sorry. Let's go back to the same example. 1,000 zero, 1,000, zero, 1,000, zero. Average is 500, right? Correct?

A. Mm-hmm.

Q. Okay. The second year, if the

average is 500, 1,000, 500, 1,000, 500, 1,000, that wouldn't spot -- that wouldn't trigger on the anomaly in that second year, right?

A. It would along the way, because, again, you're every month looking 12 months backwards. So as you continue to ramp, depending upon the rhythm of that order, the 500 would not, the 1,000 would until you get to the average -- you know, until the quantity shipped is less than 99 percent than the average.

So there wouldn't be a gap of 12 months before all of a sudden it appeared as an anomaly that we have double from one year to the next. There would be triggers along the way in getting to that second doubling in your example of the average.

Q. 1,000, zero for the first year with a 500 average, okay?

A. Mm-hmm.

Q. Second year, the order comes in -- or 13th month, the order comes in at 900, 13th month. Would it trigger?

A. No.

Q. Yet the increase in the average

would be approximately -- what is that?

A. Four times.

Q. 400 percent, four times, right? No, I mean -- I'm sorry. It would be -- the average would be 500 and the 13th month would be 900, correct?

A. That would be less than a 99 percent increase.

Q. That's right. It would be less than 99 percent.

So the 13th month, 14th month, 15th month, 16th month, all the way through the second year, that line of orders could continue at 900 and they would never pop on your anomaly list, correct?

A. In your example, yes.

Q. The beginning of the third year, okay -- so the previous 52 weeks we're all now an average of 900. The beginning of the third year, the order -- first month, third year, the order could go up to 1,700 a month. Would it trigger?

A. There would have been orders along the way leading to the increase of the average

that certainly would have triggered, yes.

Q. We just did 900, 900, 900, 900. That would not have popped in the previous -- in the second 24 months, right? If you want to do the math again, we can, okay?

A. That's correct.

Q. All right. So every month the second year, 900, 900, 900. It had gone up from -- average from 500 to 900 and that would never pop on your report, correct? You'd never look at it?

A. On the report, no.

Q. In the beginning of the third year, the order could go up to -- to 1,700, okay? Less than 99 percent, correct?

A. Mm-hmm.

Q. It would never trigger on the anomaly, correct?

A. Yes. I mean correct.

Q. So now, the end of the 12th month, month 1 to 12, the average is 500, right? Correct?

A. Mm-hmm.

Q. Second year, it's consistently 900

a month. It would never appear on the anomaly list, right? Correct?

A. I'm tracking with you, yes.

Q. Third year, it would go all the way up to 1,700. That would not pop on the anomaly list, correct?

A. Correct.

Q. So from month 12 to the first month of the third year, it could go from an average of 5- to 1,700, and there would be no pop on your anomaly list warranting any further review, correct?

A. Correct. And I might add that that would mean there would be 36 months of the same quantity being ordered in that rhythm. So it's possible, but the way most situations -- I don't know that that scenario would be likely to play out, but --

Q. And you consider the same rhythm to be month 12, 500-pill average, and month 25 to be 340 percent higher in the same rhythm? That's your definition -- that's DDM's definition of same rhythm, correct? A 340 percent increase in 13 months would be in

the same rhythm?

MR. JOHNSON: Objection.

A. The way I was tracking it is, you were indicating that there could be a long period of time by which you continue to increase your quantities received that are just below the threshold of our report. But what I was stating is that that would be quite the coincidence that a store ordered just under that level for 36 consecutive months not triggering any type of anomaly along the way. But that was your example.

Q. Let's get back to my question.

And you consider the same rhythm to be month 12, 500 dosage units. Month 25 would be 1,700, a 340 percent increase in the same rhythm, and none of that would pop on your anomaly report, correct?

A. No. If 500 was the average all along the way and then 17- became that -- that month's order, then that certainly would have popped.

Q. Here's a piece of paper.

A. I have some.

Q. Write down month 1 through 12, 500 average. 12-month --

A. Mm-hmm.

Q. -- 500 average, okay?

Go ahead. Let's write it down because we've done it three times.

Month 12, 500. You got it? I'll do it for you if you don't want to do it. Month 12, 500, okay? Month 13 all the way to month 24 -- it's the second year -- every one of those months are 900. That would not pop on the anomaly report for you to perform any further inquiry, correct?

A. That's true. I agree to that.

Q. Month 25, the beginning of the third year, it goes -- the order goes to 1,700.

A. Mm-hmm.

Q. That would not pop on your anomaly report, correct?

A. Yes.

Q. The 52 weeks prior are 900. That's a year, correct?

A. Yes.

Q. In order for it to trigger, it

would need to be 99 percent higher than the previous 52 weeks of 900, correct? That would be -- that's about 1,800.

A. Correct.

MR. JOHNSON: You already went through this and he agreed with you. Are you changing something?

Q. Fifty-two weeks are all 900. The beginning of the third year, the dosage units go to 1,700.

A. Mm-hmm.

Q. That 1,700 does not pop on the anomaly report, correct? It's not 99 percent higher than the previous 52 weeks --

A. Now that the 12 -- now that the average --

Q. That's right.

A. -- is 900 --

Q. That's right.

A. Yeah.

Q. The previous 52 weeks, correct?

So from month 12 to month 25, 13 months, the dosage units go from 500 to 1,700, an increase of 340 percent, and the

system designed by DDM to spot suspicious orders would never identify that pattern, correct, sir?

A. Not that pattern.

Q. Yes, sir.

MR. MOUGEY: Let's take a break.

THE VIDEOGRAPHER: Going off the record. The time is 2:12.

(Recess taken.)

THE VIDEOGRAPHER: Back on record at 2:31 p.m.

BY MR. MOUGEY:

Q. I asked you earlier your -- DDM's understanding of ARCOS. You understand that DDM reports its distribution of controlled substances to the DEA and that goes into a database commonly referred to as ARCOS, correct?

A. Yes.

Q. And that that ARCOS data tracks each delivery from DDM as a distributor to its own pharmacies, correct?

A. Yes.

Q. And that same data is available to DDM, obviously, and its database is from its dispensing side as well, correct?

A. The same data?
Q. Yes.
A. Yes.
Q. So if you wanted to perform analysis going back over a period of time -- DDM did -- on the trends in distribution of Schedule III hydrocodone, it could, correct?
A. Yes.
Q. And do you understand in the course of this litigation that DDM has produced its transactional data going back to the early 2000s with hydrocodone?
A. Yes.
Q. And have you had an opportunity to review the transactional data and the data that went to the DEA into ARCOS in preparation for today's testimony?
A. I did not.

- - -

(DDM-Briscoe Exhibit 15 marked.)

- - -

Q. I have two charts prepared for you. I'm going to mark them as Composite Exhibit 15, which is a combination of the ARCOS

data with the DDM transactional data, okay?

So let's start at the top left-hand corner of this page.

MR. MOUGEY: And, Corey, it is DDM 0501. You might not have it. We just got the data in. If not, that's okay.

BY MR. MOUGEY:

Q. Upper left-hand corner, you see Discount Drug Mart, correct?

A. Yes.

Q. And 6476 York Road, you recognize that as a pharmacy -- DDM pharmacy in Parma Heights, Ohio, correct?

A. Yes.

Q. And that's here in Cleveland, Parma Heights, correct?

A. Suburb of Cleveland.

Q. It's in the Cleveland area. How does that sound?

A. Sure.

Q. And the store also has a DEA number which is what's referenced in the title, BD2308155.

A. I don't have that memorized, but ...

Q. Okay. And this is a chart with month-to-month distribution of hydrocodone shipments starting in January of '99 and ending at the end of 2014, okay?

What, if anything, do you know about the transactional data that DDM keeps? And I'm kind of focusing on '99 to 2002.

A. Can you clarify?

Q. Yeah. I mean, how accurate is the transactional data that DDM has evidencing distributions to its own pharmacies dating back to January 1999 to the beginning of 2002?

A. And are you speaking of what we turned over in discovery or to what we -- we transmit to ARCOS on a regular basis?

Q. Both. So I don't have -- I have ARCOS from January 2006 to the end of '14. Okay? So all of the data to the left of January 2006 on this graph is from DDM, okay? So -- the transactional data.

So do you know that the -- are you familiar with DDM's transactional data from

January '99 to January of '06 --

A. No.

Q. -- and how it's stored or kept?

A. No.

Q. Okay. So I'm going to -- just for the benefit of the doubt here, I want to start on January of '02. Do you see where I drew the line there, January of '02?

A. Yes.

Q. And you and I just went through kind of some of the issues associated with using averages over a rolling 52-week period that was part of the system designed to identify --

A. Anomalies.

Q. -- anomalies in DDM's ordering from its pharmacies, correct?

A. Yes.

Q. Now, I'm assuming you're like the rest of us, and at some point in your life, if not still, you had a mortgage on your house and you're paying interest on your mortgage, right? You get that, right, and how interest works from the bank; they're usually compounding as opposed to simple?

Does that make sense?

A. Yes.

Q. And you understand the difference between compounding interest and simple interest? Yes?

A. Yes.

Q. Okay. And simple interest is taking just 100,000 and adding 5 percent annually, which would be 5,000 and it would be 105,000, right, and that's just -- that's straight interest.

Does that make sense?

A. (Witness nodding.)

Q. Whereas compounding at 5 percent every month -- or really every day -- whatever the daily proportion of 5 percent would be added to the balance and it kind of compounds and that builds or adds faster, compounding interest than simple interest, correct?

A. Mm-hmm.

Q. So the example that we just went through before that from month 12 to month 25, orders could increase at 340 percent without being placed on the anomaly list, you recognize

that that was kind of simple math versus kind of a compounding math on a monthly basis, right?

A. Your question is recognition of compound versus simple?

Q. Yeah, in the --

A. Yes.

Q. -- in the example we gave, that 340 percent increase from month 12 to month 25 was using simple -- which would decrease the -- which would reduce the 340 percent that it -- I'm sorry, bad question -- that using simple averages as opposed to kind of monthly compounding would reduce the impact over time of what orders would escape the rolling 52-week average, right?

MR. JOHNSON: Objection.

Q. Is that question awkward?

A. In the hypothetical example you provided and as you just described it, that is true.

Q. Okay. So the example we have in front of you is a real world example of a -- one of DDM's pharmacies out of the 60 or 70, and if you look back in the early 2002, 2003 range, you

can see that the average hydrocodone dosage units -- excuse me -- per month are somewhere in the 3- to 5,000 range, 3- to 6,000 range; is that fair?

A. What period of time, sir?

Q. Early '02 to '03.

A. Yes.

Q. Okay. And, again, that's just rough. I'm not asking you to calculate the lines there. But somewhere in the 3-, 4-, 5,000 range average per month, maybe 6,000, right?

A. Yes.

Q. All right. And if you go then to the 2004 to 2005 to 2006 to 2007, you can see that the average increase is growing, correct?

A. I see fluctuation in the average, but the overall trend is growing, yes.

Q. Yes. I mean, if we were to draw a line from the average from year to year to year, over time that average is increasing, correct?

A. Again, first I've seen this, but it would be interesting to know the impact that the decrease in the months that are a valley, so to speak, how that balances out the overall

growth.

Q. Well, it really doesn't take a math Ph.D. to figure out that the line, even if you take the valleys -- looks something like that with the pen on there, correct?

A. Again, first time I had a chance to look at this, but does that line flatten out whenever you look at every month in its totality as a sum. And, again, it's the first I'm looking at this.

Q. So you believe that you can't see a trend from 2002 to 2013 and '14 that the average dosage units go from 3-, 4-, 5,000 to here we are in '14 to somewhere in the 13-, 14-, 15,000?

A. I can see that.

Q. Okay. That doesn't take a lot of analysis to figure out, right?

And so the trend from '02 over the period of a decade at this pharmacy in Parma, Ohio, goes from 3- or 4- or 5,000 pills per month to -- or dosage units per month to somewhere in the 14-, 15,000 pills per month, correct?

A. Yes.

Q. And kind of based on the math that we went through, unless a monthly order exceeded the 52 months rolling average by 99 percent, it would not have popped on your anomaly report, right?

MR. JOHNSON: Objection.

A. Correct.

Q. And so this trend going from 3,000 increasing to the tune of roughly 500 percent over the course of a decade, unless one month in particular would have increased by 99 percent over the previous 52 rolling weeks or it would have popped on the six-week average or fat thumbs report, it wouldn't have come to your attention, right?

A. On that report, no.

Q. Now, if the amount of dosage units going into the State of Ohio, but more specifically, the Cleveland surrounding area in Parma Heights, increases from 3- to 4-, 5,000 dosage units in some pharmacies up 4- or 500 percent, would that have caused DDM any reason for concern as we get to 2012, '13, '14

that would warrant any investigation into pharmacies, specific pharmacies?

MR. JOHNSON: Objection.

A. I need you to repeat that if you don't mind.

Q. Would increase -- looking at the chart that we're looking at right now, dosage units increasing from 3-, 4- or 5,000 dosage units per month to 13-, 14-, 15,000 dosage units per month going into one store in Parma Heights, Ohio, would that cause DDM any reason for concern?

MR. JOHNSON: Objection.

A. The answer is possibly. And, again, not -- not having seen this prior, we would look to see what the growth of the rest of the prescription business would be. And if this were a new store that over time they're building business with new prescriptions and their opioid growth is commensurate with their overall prescription growth, that would be an example where that wouldn't be as concerning.

Q. That's a great example. So one of the metrics that -- I'm glad you brought that

up.

So one of the metrics that DDM could have used over this period of time would have been controlled substance prescriptions percentage compared to overall prescription percentage, correct?

A. Yes.

MR. JOHNSON: Objection.

Q. And that is a metric that's often used in the industry to help identify problems with specific orders, correct?

A. Possibly.

Q. Yeah. And you've seen -- DDM has seen other vendors over a period of time approach it with different metrics than some of the rolling averages that you referenced earlier, right?

A. Yes, sir.

Q. And one of those different metrics that was proposed by an outside vendor was the percentage of controlled substance prescriptions as compared to the percentage of overall prescriptions, right?

A. Okay.

Q. So can you point me to any policy or procedure or automation that your pharmacies, your customers, like the one in front of you, looking at or analyzing or reviewing their percentages of controlled substance prescriptions as compared to overall prescriptions as part of the automation process?

A. No, sir.

Q. So when you received an anomaly on that report over the last decade, was it part of the regular process for DDM to run metrics like percentage of controlled substance prescriptions as opposed to overall prescriptions?

A. Not to my knowledge.

Q. So that's another metric in addition to the one we discussed earlier about looking at the higher risk prescribers that are writing a disproportionate number of controlled substance prescriptions as opposed to their overall prescriptions, correct?

A. That would be another example, yes.

Q. And those are both metrics that were being discussed in the industry in early

2000s, mid 2000s that DDM did not use to identify suspicious orders on a regular basis, correct, sir?

A. Yes.

Q. If you would, sir, turn to page 2 of Briscoe 15. And here's another example -- now, Euclid, Ohio, that's where -- that's where DDM was originated, correct? Am I losing --

A. Elyria.

Q. Okay. All right. Close.

Where's Euclid, Ohio?

A. It's east, so along the Lake.

Q. Okay.

A. Northeast.

Q. And, again, so this is Euclid, DDM, hydrocodone, has the DEA number, total dosage units. But if we do the same thing we did in the last chart and look sometime the beginning of 2002 into 2003, the average dosage units appear to be somewhere around 3- or 4,000, depending on what time period you're looking there; is that -- is that a fair look at that?

A. Yes.

Q. Okay. And by the time we get into

2011 and 2012, if we do the same kind of trending analysis, very sophisticated with my pen, it gets us somewhere into the 8-, 9-, 10,000 dosage units per month, correct?

A. I would say that the height of the peaks is certainly trending in that direction. I'd be curious to know if we used a different method to analyze, what the valleys would do to the impact of an annual view to this chart.

Q. All right. But as you said before, you've never seen this data or attempted to run that analysis? And I say "you," I mean that you've seen from DDM, correct?

A. Not to my knowledge.

Q. So Peter Mougey, some redneck lawyer out of Pensacola, Florida, running DDM's analysis is kind of the first time you've seen this?

MR. JOHNSON: Don't be so hard on yourself.

MR. MOUGEY: I'm still working on it.

A. Not the first time I've seen a report like this, nor not the first time I would

have run a report like this. But the way you phrased the questions earlier specific to the way we distribute products and leading to an anomaly populating on the report, no. But I'm familiar with that metric and it has been utilized in some reports on demand that I've run in the past.

Q. So let's look at -- in preparation for today and as part of DDM's responses to discovery --

MR. JOHNSON: I'm sorry. Are you in the middle of a question?

MR. MOUGEY: No. Go ahead.

(Discussion off the record.)

- - -

(DDM-Briscoe Exhibit 16 marked.)

- - -

BY MR. MOUGEY:

Q. All right. I'm going to hand you -- Mr. Briscoe, I'm going to hand you what we're marking as Briscoe 16.

A. Thank you.

Q. And in preparation for your testimony today, have you seen what I've just

put in front of you marked as Briscoe 16?

A. I believe I have, yes.

Q. Okay. And your counsel forwarded this to us last Friday afternoon, and we were trying to get the answers to DDM's suspicious order monitoring policies and procedures and try to put some kind of meat on the bone, so to speak, okay? And Judge Polster ordered the Defendants to give us some answers to a few questions, and I want to take you through a couple of those, the ones that relate to your suspicious order monitoring policy.

So who would be the right person to talk to about the transactional data, those two charts that we just went through from like '99 to 2002, and what's there and what's not, is it accurate, are we missing, is there holes -- who would be the right person that would know that?

A. So I believe both have been named. The previous director or VP of IT, her name is P.J. Ferut.

Q. Okay.

A. And then our current director of

IT is Keith Miller.

Q. All right. So P.J. Ferut could help --

A. P.J. Ferut and Keith Miller.

Q. Okay. Perfect.

All right. Number 2 is "Please produce each of your Suspicious Order Monitoring System (SOMS) policies and procedures since January of '06 and identify the Bates stamp range for each. Please identify the effective dates each was in force and effect."

Did I read that right?

A. Yes.

Q. Bear with me here, Mr. Briscoe. I just thought of something I forgot to look at beforehand.

Now, your counsel was kind enough -- as you can see here, it says, "To the extent the Bates range stamps are needed, we will supplement." Okay? And we did inquire to try to get the Bates ranges. And I'm going to -- if the last few hours wasn't awkward enough, this might be worse, because we got those with working with your counsel yesterday

about 1:30, and we were already en route here. So I don't have a real good command of where we are with all these, and they're a big stack, okay?

So what I want you to do is not worry about the stack so much, but recognize that I might not have a real good command of the stack. And I just have a few questions.

So do you believe that from January of '06 that the suspicious order monitoring systems, policies, and procedures are in writing within DDM evidencing what the formulas and the methodology was?

A. In writing from 2006?

Q. Yes.

A. I don't believe so.

Q. Do you know when, at what point in time, there was something in writing evidencing DDM's system that was designed to identify suspicious orders, when was that put into writing?

A. I don't know.

Q. Do you know if it was ever put into writing?

A. I know that in preparation for, you know, these documents in my deposition, we formalized by describing what our policies and procedures are.

Q. Now, what do you mean by that, "In preparation for these documents in my deposition we formalized by describing ..."? What do you mean?

A. Meaning I did not go to a document or a policy and procedure that was created to hand over as describing our -- the way that we operated.

Q. That would have made it real easy, wouldn't it?

A. Yes, it would.

Q. Because it really -- there wasn't anything in writing, right?

A. I think there were components in writing. I don't know that it was -- that all the dots were connected in a policy and procedure.

Q. Let's make it -- let's maybe see if we can connect some of those dots, okay?

The 52-week average report that we

kind of went through in detail, in writing anywhere?

A. On the description of the report on the top of the report, the guts of what created the math associated with the report, those were in writing related to how the report was generated from an IT perspective. So in the systems and the way that they create reports, there was that historical information on how that report came to be and what its purpose was.

Q. All right. So you believed -- did you help with identifying what documents were responsive to this Number 2?

A. Yes.

Q. Okay. And let me tell you where I'm struggling a little bit, okay? So I got the stack in and it's fairly significant. Okay? We got the Bates ranges, which is helpful, but in preparing for today, I'm just going to give you some problems where I had a little bit of trouble.

So in response to this -- like, for example, Bates Number 242 is titled Temperature Management System Healthcare

Specifications, where we've got specifications for keeping the humidity and the moisture in the -- in some of the distribution centers, right? There's several documents. And they're not a ton, but there's several, and that's just an example.

I wouldn't think that -- and you can correct me if I am wrong here, but managing humidity in the distribution centers is kind of what we're driving at when we're looking at -- for suspicious order monitoring systems policies and procedures. Do you -- if you want me to hand it to you, I can.

A. No, no. No, I think that was just included as the -- one of the policies associated with the distribution center and our pharmacy warehouse and their operation. So we didn't withhold any of the policies and procedures that were in place based on the topic of the procedure.

Q. Right. But, more importantly, let me hand you what I've marked as Briscoe 17.

- - -

(DDM-Briscoe Exhibit 17 marked.)

- - -

Q. And this is one of the documents that was identified as responsive to Number 2, and it says, "Please produce each of your suspicious order monitoring system policies and procedures since January 1, 2006 and identify the Bates range for each. Please identify the effective dates each was in force and effect." Okay?

So we're sitting here trying -- from the outside in trying to figure out what's going on. So does this document have -- does that -- does this give us any helpful information to try to discern what DDM suspicious order monitoring system policies and procedures were from January 1 of '06 to the current date?

A. No. I don't recall this being one of the documents associated with the different policies and procedures that we pointed to related to SOMS.

Q. Okay. Let me give you what I've marked as Briscoe 18.

- - -

(DDM-Briscoe Exhibit 18 marked.)

- - -

Q. Now, before I ask anything specific about this document, do you recognize the -- kind of the format or the layout of this document?

A. Yes.

Q. What is this?

A. This is Policy 110 of the Verified-Accredited Wholesale Distributor accreditation that we received in 2017, which was a rigorous review of our policies and procedures, an on-site survey of our business practices at the distribution center, to ensure that there's security and we are safely distributing prescription medications.

Q. I might get some of this mixed up here, but as of 2017, you all were not distributing any Schedule II or Schedule III any longer, correct?

A. As of '17 --

Q. Yes.

A. -- no longer Schedule II.

Q. Okay. Still Schedule III? I'm

getting my pharmacies mixed up.

A. Yes.

Q. So have you received any feedback yet on that accreditation process from 2017?

A. Yes.

Q. All right. And has that been memorialized in writing?

A. I'm not sure, but I believe we were accredited or we passed. You know, VAWD certification I think might be the correct term.

Q. What was that acronym that you just used?

A. VAWD, V-A-W-D.

Q. All right. So every time I see one of these policy numbers like we're looking at here in Briscoe 18, this is -- would you refer to this as a manual?

A. There were two sets of information specific to the distribution center's day-to-day operations --

Q. Okay.

A. -- one of which was labeled VAWD accreditation, and the other, I believe, was labeled as pharmacy warehouse manual or pharmacy

warehouse policies and procedures. And there was a lot of redundancy between the two because a lot of the policies and procedures they had written satisfied or led up into the way that the VAWD needed to be organized with each segment that they would be reviewing.

Q. Okay. Were all of these policies all kept in one place? So this is policy 110. I'm assuming there's policy 1 through 109 before this?

A. There's 101 through -- I believe maybe 116, but don't quote me.

Q. Okay.

A. I don't think --

Q. But you think there's somewhere around 15 or 20 of these?

A. Specific to the VAWD process, yes.

Q. Okay. All right. Now -- and, again, I apologize for not having all the lingo down yet, but are these out of a policy and procedures manual that exist somewhere else?

A. The -- what led to the VAWD policies and procedures?

Q. Yes.

A. -- stemmed from written policy and procedure from the pharmacy warehouse. So, again, I think what might have been produced to you was two chunks of information labeled in a different manner where there would have been some redundancy.

Q. So, again, the document that we're looking at at Briscoe 18, policy 110, this is a process for ensuring drugs and devices are stored at temperature standards according to the drug device labeling and/or USP standards, right?

A. Mm-hmm.

Q. And that doesn't really help me with trying to figure out the suspicious order monitoring system at DDM, does it? I'm just a little -- making sure I'm not missing something here.

A. No. I'm not missing anything I can't think of.

Q. Okay. So if we can go through it, here's Briscoe 19, policy 111.

- - -

(DDM-Briscoe Exhibit 19 marked.)

- - -

Q. And, again, another reference to humidity and standards in -- in -- and that's -- I'm not missing anything. That's not really helpful to us.

A. It was not removed as part of what we concluded that surrounded activity in the distribution center.

Q. Okay. So let me make sure I understand. When you're saying they were pulled from -- did you say inventory warehouse or a policy or what did you -- what were you -- what did you refer to it as?

A. Well, so using the term synonymously, our pharmacy warehouse --

Q. Right.

A. -- is also our distribution facility.

Q. Right.

A. So in 2017, maybe prior to that, we went through the -- made the decision to go through the process of VAWD certification.

Q. Okay.

A. And part of VAWD certification is

making sure that you have policies and procedures in place and they are rigorously vetted by the accrediting group. And part of the end result of that process led to having these policies and procedures labeled 101 through whatever number they end in.

Q. Okay. Now, are you familiar with workshops that were put on and offered to DDM for suspicious order monitoring and developing policies and procedures that would help assist DDM in putting its policies and procedures in place?

A. I never attended a workshop.

Q. All right. I guess where I'm going is, there is no question in your mind that DDM had designed, implemented, and operated a system designed to detect suspicious orders from 2006 until 2016?

A. Rephrase or -- I'm sorry -- reask.

Q. Sure. There's --

MR. JOHNSON: Do you want him to reread it?

MR. MOUGEY: No, I've got it.

BY MR. MOUGEY:

Q. There's no question that DDM had designed, implemented, and operated a system to detect suspicious orders from 2006 until 2016?

A. I truly believe that -- again, I don't like the phrase, but the totality of our efforts in the way that we operate in the distribution center, the fact that we do not have customers and we're not making sales, we are distributing to our own stores for which we were very familiar and have direct control over, I'm confident in saying that we did not have a suspicious order in that time frame.

I would never say in any segment of our business that, you know what, we have it completely figured out and there isn't ways that we can continually look at room for enhancements, et cetera, but I'm confident in saying that we did not have any suspicious orders from that facility during that time.

Q. But the question I asked you was a little bit different. The question I asked was not whether you're confident there were suspicious orders, but whether or not DD --

MR. JOHNSON: Were not -- were not suspicious orders you mean?

MR. MOUGEY: Yeah. Yeah, whatever I said.

BY MR. MOUGEY:

Q. But the question I asked was a little bit different, which is, there's no question DDM believes it had designed, implemented, and operated a system to detect suspicious orders from 2006 until 2016?

A. We did design a system to detect, yes.

Q. And from 2006 until 2016, DDM had that system designed -- that was designed to identify suspicious orders of controlled substances?

A. Yes.

Q. And have you seen any discussion internally at DDM that there was not a policy or a procedure in place?

A. I don't believe so.

Q. Because if, in fact, DDM did not have a system that was effective to identify suspicious orders and then report them to the

DEA, it would have violated its obligations under the Controlled Substances Act and the regs promulgated thereunder, correct?

MR. JOHNSON: Objection.

A. We had a system --

Q. Right.

A. -- and we did not identify any suspicious orders; therefore, we did not report suspicious orders.

Q. Now, who was in charge of pulling these policies -- I think you said 101 to 116 or somewhere thereabout together and ensuring they were accurate?

A. So Jill Strang, who we've talked about earlier, and then the SVP of pharmacy who's on the license of the distribution center, his name is Pete Ratycz.

Q. All right. So Mr. Ratycz and Ms. Strang are both people you have worked with for quite some time, correct?

A. Yes.

Q. And they are more than capable in their positions, correct?

A. Yes.

Q. And they're certainly not going to gather information and submit it to an accreditation board that wasn't accurate, right?

A. Correct.

Q. And you believe that they did their homework when putting together that -- those reports for the VAWD certification, correct?

A. To my knowledge, yes.

- - -

(DDM-Briscoe Exhibit 20 marked.)

- - -

Q. Hand you what we've marked as Briscoe 20. And, sir, this is a policy titled Inventory Controls dated 12/1/2016, correct, sir?

A. Yes.

Q. And it's dated -- it's -- I'm sorry -- policy number 112, correct?

A. Yes.

Q. And the purpose is process to identify any inventory concerns, cycle counts, losses or theft, correct?

A. Yes.

Q. And the folks putting together this policy for the accreditation, after doing their homework and analyzing DDM's policies and procedures, came to the conclusion that "We do not" -- and I'm in the first paragraph -- "We do not sell any items outside of our own company, so there is no policy in place for ordering patterns or payment amounts that would identify potential diversion or criminal activity."

Do you see that, sir?

A. I do.

Q. Is that an accurate statement?

A. I think that's a poorly written portion of that policy.

Q. Yes, sir. And have you seen this in preparation for your testimony today?

A. I believe I've seen it. I don't know that that section landed on me as I was preparing.

Q. So this went out to -- this came from the senior VP of pharmacy, correct?

A. I believe Jill authored the policies and, you know, he's listed as the responsible pharmacist.

Q. He signed them, I believe. He signed -- is on the distribution license, correct?

A. Yes.

Q. And this was approved by one of the most senior people in DDM's organization, correct?

A. On the pharmacy side, yes.

Q. Yes, sir. And based on the direct reports to him and the information provided to him, he approved the language that there's no policy in place for ordering patterns or payment amounts that would identify potential diversion or criminal activity, correct, sir?

A. That's what's written there, yes.

Q. Yes. And if that is an accurate statement, sir, written by a senior vice president of DDM, DDM did not comply with the Code of Federal Regulations 74 requiring a system designed to identify and report suspicious orders, correct, sir?

MR. JOHNSON: Objection.

A. We did have a system in place that we utilized that we described. You saw 11

examples of due diligence, which is Phase 3 of that example. This is just a poor characterization of what that -- that procedure is and was living and breathing and active.

Q. Was the living and breathing and active system that you designed, was it secret within DDM?

A. No.

Q. Was it kept in a -- under a lock and key in your filing cabinet in your office?

A. No.

Q. Was it -- did you hide it from the senior VP?

A. No.

Q. Did you report on it regularly in meetings with the senior VP and tell him what you were doing?

A. No.

Q. Did you keep him up to date on all of the activity that DDM was doing regarding the analysis and the system designed to identify suspicious orders?

A. It probably has come up in conversation, but we didn't have regular

meetings.

Q. But you can't point to anything specific?

A. Not as I sit here today.

Q. So this system that was designed to identify suspicious orders in compliance with the Code of Federal Regulations promulgated under the Controlled Substances Act was such a part of the day-to-day conversation at DDM and the reporting at DDM and part of the culture of DDM that the senior vice president of operations signed off on the VAWD accreditation that there was no policy in place for ordering patterns or payment amounts that would identify potential diversion, correct, sir?

MR. JOHNSON: Objection.

A. I would indicate that this policy and this process of going through VAWD accreditation took place in 2016. This was beyond a point in time whenever we had, you know, hydrocodone products in our distribution center. That's not -- that's not an excuse, but whenever you indicate that we're not having daily conversations associated with this topic

and how we handle suspicious order monitoring, there is -- there is very little activity as a total bucket of our distributions from that distribution center that are controlled substances and even fewer products that are opioids. And that does not excuse having a policy and a procedure and a system in place, but I can assure you the system has always been in place.

This is a poor characterization, an inaccurate characterization of the activity that surrounded our approach to suspicious order monitoring.

Q. Do you see what date this poor characterization was adopted on this document, sir?

A. Yes.

Q. And what date is that?

A. Well, it was accepted -- adopted on 12/1 of '16.

Q. Yes, sir. And it's such a poor characterization and it -- it so mischaracterizes DDM's true policies that it was updated on March 1st, 2017 and continued to be

adopted in this process, correct?

A. Three months later, yes.

Q. Yes, sir. And do you know how long this statement contained and remained in this report?

A. I don't -- I mean, to my knowledge, if we produced it in this manner, it hasn't changed from the time it was adopted.

Q. So as of today, 2018, December, you believe that policy 112, the senior VP stating that there's no policy in place for ordering patterns that would identify potential diversion, this has never been changed?

A. Again, I would say yes, it's our -- our procedure, what we actually do has not changed. And also accurate is this paragraph, which is a poor representation of reality, has not changed.

Q. Policy 112 in this memorandum that you in front of this jury today is saying is inaccurate but it was signed by the senior vice president and then updated three months later and continued to be approved is still in the language today, yes or no?

A. It is. It is. May I add that it's not impactful to the way that we operate.

Q. Yes, sir. But it might be impactful to the people in the State of Ohio that have seen hydrocodone distributions dosage units go from 3- or 4,000 on average in a pharmacy up to 14- or 15,000 over a period of years. Do you think it might be impactful to them?

MR. JOHNSON: Objection. You're just arguing with the witness.

Q. You think it might be impactful to them?

A. What I'm saying is we're continuing --

MR. JOHNSON: Objection.

A. -- to execute on the processes we have in place. They're just not characterized well in that paragraph.

Q. Exactly. And during the time period when -- you and I just went through the formula used where it could -- in a period of 13 months, dosage units could increase by a period -- by an amount of 340 percent using

simple math, that was -- that wasn't impactful to the people in the State of Ohio?

MR. JOHNSON: Objection.

A. Again, your hypothetical would have had to have happened in a way that it perfectly stayed underneath 99 percent as it grew to that number without invoking an anomaly.

Q. Yes, sir. And what I then demonstrated after you pointing to the fact you thought it was a hypothetical is, in fact, close to reality, that the dosage units dispensed out of DDM's own pharmacies in the Cleveland area increased 3- to 400 percent, and it's very possible, using the formula DDM supposedly employed, that that never triggered one of the anomaly reports that you reviewed, correct?

MR. JOHNSON: Objection.

A. It's possible.

MR. MOUGEY: This is a good time for a break.

THE VIDEOGRAPHER: Going off record, the time is 3:18.

(Recess taken.)

THE VIDEOGRAPHER: We're back on

record, 3:28.

MR. MOUGEY: I don't have any further questions at this point. I do -- just wanted to note that DDM did respond to Judge Polster's order on Friday, actually before the deadline, and we reached out to DDM and they --

MR. JOHNSON: Bates-stamped?

MR. MOUGEY: Yes. They didn't put the Bates stamps in the actual response. We reached out on Friday, like ten minutes after that you all filed, asked for the Bates stamps. DDM did get us the Bates-stamped documents.

Today is Thursday. We got them Wednesday and we were en route. I did not get a chance to go through them.

I don't anticipate any issues, but I do want to keep the deposition open in the event that when we do get through the Bates stamps pointed out to us yesterday in more detail, if I see any issues, I do want to reserve to keep it open. And, of course, I'll reach out to

DDM's counsel, Tim, before I do anything else, but I did want to reserve that on the record.

MR. JOHNSON: Oh, no problem. And, just to be accurate, I think Jeff at least communicated with me on -- let's see, today's Thursday -- that would be Tuesday and asked for them by tomorrow, which would have been Wednesday, and we did get them to him.

But I totally understand that you've only had them a short time and that doesn't really change anything.

So I don't have a problem with that.

MR. MOUGEY: Okay. I don't have any further questions at this point.

MR. JOHNSON: No, nothing.

MR. MOUGEY: Thank you.

THE VIDEOGRAPHER: This ends today's deposition. We are going off record at 3:30 p.m.

(Signature not waived.)

- - -

Thereupon, at 3:30 p.m., on Thursday, December 6, 2-19, the deposition was concluded.

- - -

CERTIFICATE

STATE OF OHIO :

SS:

COUNTY OF _____:

I, JASON BRISCOE, do hereby certify that I have read the foregoing transcript of my cross-examination given on December 6, 2018; that together with the correction page attached hereto noting changes in form or substance, if any, it is true and correct.

_____

JASON BRISCOE

I do hereby certify that the foregoing transcript of the cross-examination of JASON BRISCOE was submitted to the witness for reading and signing; that after he had stated to the undersigned Notary Public that he had read and examined his cross-examination, he signed the same in my presence on the _____ day of _____, 2018.

_____

NOTARY PUBLIC - STATE OF OHIO

My Commission Expires:

_____, _____.

CERTIFICATE

STATE OF OHIO :
SS:
COUNTY OF FRANKLIN :

I, Carol A. Kirk, a Registered Merit Reporter and Notary Public in and for the State of Ohio, duly commissioned and qualified, do hereby certify that the within-named JASON BRISCOE was by me first duly sworn to testify to the truth, the whole truth, and nothing but the truth in the cause aforesaid; that the deposition then given by him was by me reduced to stenotype in the presence of said witness; that the foregoing is a true and correct transcript of the deposition so given by him; that the deposition was taken at the time and place in the caption specified and was completed without adjournment; and that I am in no way related to or employed by any attorney or party hereto or financially interested in the action; and I am not, nor is the court reporting firm with which I am affiliated, under a contract as defined in Civil Rule 28(D).

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my seal of office at Columbus, Ohio on this 11th day of December 2018.

_____
CAROL A. KIRK, RMR
NOTARY PUBLIC - STATE OF OHIO

My Commission Expires: April 9, 2022.

- - -

DEPOSITION ERRATA SHEET

I, JASON BRISCOE, have read the transcript of my deposition taken on the 6th day of December 2018, or the same has been read to me. I request that the following changes be entered upon the record for the reasons so indicated. I have signed the signature page and authorize you to attach the same to the original transcript.

Page Line Correction or Change and Reason:

Date ________________ Signature ____________________________